

Certificate of Need – ASF Rules

Notes for Stakeholder Meeting – September 16, 2015

WAC 246-310-020

Introductions, very brief overview of previous stakeholder meeting held August 17, 2015.

Department provided answers to three questions developed from first meeting. The first question was:

Q1: Why did the definition of a facility change to an operating room?

A1: The department has not changed the definition of healthcare facility. An ASC is a facility with operating rooms.

Emily raised a number of questions, including how DOH defines “health care facility.” Generally, how does the department distinguish between expansion versus an establishment of a new healthcare facility? Indicated that the original question was not specific to ASF, but “it was rather to any new health care facility and what criteria the department was looking at. “The more important fundamental question that is really important to answer at the outset is what qualifies, what criteria, what type of activity constitutes the establishment of a new healthcare facility. For example, is it issuance of a license fee required to establish a new health care facility?” (3:41)

Bart asked for more examples of what Emily described and how it is going to be focused for this conversation because in some cases, some of the things referred to as health care facilities aren’t bricks and mortar, and may be a service or services.

Emily asserted that this seems like a very result oriented rulemaking “...where we have a particular increase in the past or expansion and the department wants to subject to C of N review.” “I’m trying to understand how does the department understand what establishment of a healthcare facility is just as a general proposition. Because really, the department could label anything as the establishment of a new healthcare facility that it wanted to and I’m trying to understand, generally, what type of, how does it distinguish between an expansion and establishment of a new healthcare facility, generally.” (5:43)

Sometimes physical location is an indicator of a new healthcare facility.

Brief discussion of case law; case where hospital wanted to provide in-home services. Court described this as hospital assuming new identity for purposes of CoN.

Emily indicates that this was really the nature of her question in the last meeting – “...that is articulation as to when, from the Court, C of N might be required for assuming a new identity or

essentially becoming a new type of healthcare provider. So the question that we asked was not when an ASF was subject to C of N review, that seems like what we're talking about specifically to this rule, but to understand why the ASFs and OR additions are being singled out as opposed to other types of facilities where [there are] additions to the facilities, sort of what is the criteria, generally, for understanding when an activity is the establishment of a healthcare facility, especially when this is going under a definition in the rule, sort of really understanding how to distinguish between one type of activity and the establishment of a new healthcare facility, and another not." (8:29)

Jody asks for clarification.

Emily restates her questions and understanding of history of the rule. Indicates that her original question was not specific to ASFs. In current rules, OR increase isn't subject to CoN review.

The second set of three questions were presented and answered as follows:

Q2A: Do criteria exist to determine whether ASF expansion qualifies as a new health care facility?

A2A: Yes, if a facility expands the surgical capacity (increase in OR's).

Q2B: Does the department rely on this criterion to determine whether an ASF is subject to certificate of need review?

A2B: Yes.

Q2C: When exactly is a new health care facility established?

A2C: When the facility meets the definition of ASC in current rule or expands the surgical capacity by increasing the number of OR's.

Frank and Jody ask for clarification as to existing rules and definitions, implied and otherwise.

Emily wants to understand the difference between increase and establishment.

Bart brings conversation back into focus of instant rulemaking. "This rulemaking is about ASF and whether they add capacity to a previously approved ASF should be subject to CON. Just as we have in rule tried to create a definition of ASF that is subject to review and those that aren't, which isn't clear in statute. Discussion as to what is and isn't subject to review and the legislative thinking behind it is another very lengthy discussion that goes back many years. The statute says ASF are subject to review. All of our rules are result oriented. The result is do we believe that an Increase in OR capacity/facility changes capacity and impacts access, so CoN is concerned about increase. If it didn't exist before, then it must be new. Department cannot "black and white" this issue – we can't apply a matrix and come up with the same answer because we've conceded that there are unique circumstances for each of the things we're

looking at that make sense. We don't have everybody that does ORs subject to CoN. We created exemptions for this.

Jody just wants to know what the rules are – why don't we put an "f" in the rule that adds clarity?

Was that the job of the legislature? Emily isn't looking for black and white, but thinks factors to be considered, like licensure issuance are important to have because it helps safeguards against arbitrary selection by the department about increases in capacity or other types of undertakings subject to review.

If consensus can be reached on rule, that would be great. We can't rely on licensing, however. No connection between license and CoN. There's no connection to CoN and being Medicare certified. But many aren't. Linkages are difficult to identify.

Susie indicates that this feels like it's focusing on one type of facility, "...and this translates for me as what is good for the goose is good for the gander." She does not feel comfortable with that focus on just one type of facility.

Emily: "We're talking about definition that has general applicability to all health care facility types that are subject to C of N review. The establishment of a new health care facility is not a definition that is specific to surgery centers so if the department says an increase of this type, of certain increases in capacity what are and what are not subject to review seems like it ought to be thinking about healthcare facilities from globally so if you get an issuance of a license or issuance of a new Medicare number to the department, the department can view this as "you are a new healthcare facility" – that would be something that would be, should be generally applicable to all healthcare facility types that are subject to review. That is something that is not result oriented as the department is saying certain changes to a facility that has a C of N review make that facility no longer an existing facility but making it a new facility." (21:43)

What happens if you have substantive change? An out of the ground, new facility.

Figuring out what makes something new is an important question and that criteria should be applied to all facilities that are subject to review.

The department does not believe that we're going to get there – it is not that simple. Unique nature and characteristics of a particular facility need to be reviewed as well as access to quality, and cost.

Frank: This can be one thing that differentiates hospitals from ASF.

Jody describes a hypothetical re substantially different projects – three rooms for pain management are acquired by another entity and overnight becomes a 15 room orthopedic specialty center. That's where some of this started. Project is so substantially different than what you originally sought a CoN for that this is what triggers review.

Emily thinks this scenario on the spectrum of changes in ASF is “way down on the bottom.” If the concern is a targeted concern to particular changes and expansions, can we look at that specifically rather than something that is so broadly applicable to all surgery center changes.

Bart: Any change in ASF if it didn’t exist yesterday its new. There might construction or development or other establishment. You built it, you developed it. It is intended to include facilities that don’t require buildouts.

Discussion between Bart and Susie re the definition of “new.”

Jan: We have a clear example in rule. Home health and hospice agencies. If an existing agency wants to provide services in another county, they are a new health care facility and require a CoN. This is along the same lines that we’re saying here with ASC. We are defining what that means for that particular type of entity. It does not require a new license, no new Medicare certification. It’s been in our rule for a long time.

Bart: There are interesting cases where “new” turned on whether the facility qualified for a new license. The Courts ruled that yes, that’s new. We understand they weren’t there. It isn’t black and white. We have cases where we have new bricks and mortar and it isn’t considered new. In this case, I’m not sure that we are going to answer your question satisfactorily. But we do believe that when you expand OR capacity in an ASF, that should be treated as new and subject to review.

What about shelling in rooms? If your CN says you are approved for 2, and you’ve made provisions for 3, to us, your CN has changed and you would now be approved for additional capacity. Particularly today, when the whole methodology is determinate on what is the capacity of an OR. The whole thing hinges on projecting what is the use of an OR, and how many we approve.

020 will be clarified regarding language.

Proposed language except was distributed to group.

The third question was introduced and answered:

Q3: What are the factors stakeholders and interested parties can evaluate to help them understand that this isn’t a result oriented undertaking?

A3: The department did not understand this question. We request elaboration or an example.

Inventory - how are we going to monitor this?

Department has an internal verification process – any increase in OR is monitored.

Jody asked for a current list of OR and how many rooms they have. Any increase in OR is subject to review; it would be nice to know any discrepancies ahead of time. Advance reconciliation

would be great. Identify how many ORs currently exist and where. Will department records match what is really out there.

Bart: Until this rule becomes effective, we're not retroactively applying the rule –Can we reconcile the number of ORs – licensed or Medicare certified. What they are today is what we're counting. We're giving benefit to the doubt of where we made the determination where someone wasn't subject to review.

Jody: Thinks it would be a good safety valve to have reconciliation before rule goes into effective.

Bart: We can provide you with what we have. Here's everything that we know about.

Frank: When you say OR, does that include procedure rooms?

Bart: Looking at nature of room – construction standards. What differentiates what type of surgical procedure may be appropriate to be provided in that room.

Ana: Comment about proposed language. Ambiguous for facilities that have expanded, and how they will expand in the future. Take last sentence of proposed language out entirely. Second problem: to the extent there is a different number of ORs, original approval for OR might be different from a later decision. As written, CoN may be approved through other sources like an ALJ.

Bart: We will work on language. Language will reflect what you were approved for through whatever the process is, and if you make that change, that's a new CoN application. We'll try to make the distinction more clear.

Ana: should also say "ambulatory surgical facility" as opposed to "ambulatory surgery facility."

Jody: Relocation language is missing

Bart: Relocation will likely be addressed in methodology.

Discussion of next steps:

- Department will re-work language
- Get draft language out quickly for group comment
- There is interest to move this portion of the rule forward quickly
- Department anticipates having CR 102 in place by January 2016
- Proposed placement for language in existing rule: under 1(1)(a) new (iii).

Break.