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RE: Comments on Current OR Methodology

Drs. Ullrich and Greene,

Thank you for the opportunity to provide comments on the operating room methodology for discussion by the workgroup. While I am eager to see comments from many others across the state, I have developed a few thoughts based on my experience and the issues I have noticed as I have worked with providers of surgical services. While I certainly do not have the solution to all of these challenges, I hope the brief discussion of each below can stimulate a fruitful discussion among the workgroup members.

1. **Safety and Quality, Access and Value**

   When the current methodology was adopted, the Quality, Access and Value workgroup had not yet met, and the results of their work—the revised and enhanced Basic Principles—had not yet been developed. While I understand that the hope for the workgroup is to use the current methodology and tweak some assumptions, rather than starting with a completely new methodology, I would encourage us to examine each step in whatever methodology is recommended in light of these basic principles. In particular, we should ensure that each step of the revised methodology is governed by these principles, as data and utility allow. This concept is particularly important when considering the challenge presented in the next point below.

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2. Hospital-based versus ambulatory (freestanding) operating rooms

The current methodology considers total need for operating rooms, combining utilization and need for hospital-based and freestanding (ambulatory rooms not in a hospital-based setting). This feature is helpful in allowing maximum flexibility for potential certificate of need applicants to determine what type(s) of operating rooms to propose, as well as allowing providers with existing ORs to change their designation (hospital-based to/from freestanding) more easily. However, it also incorporates incongruences into the methodology and makes developing a methodology that applies to all operating rooms more difficult.

For example, hours of operation are likely to be vastly different between hospitals and ambulatory surgical facilities, and even between community hospitals and larger tertiary facilities. The current methodology assumes nine hours per day, 260 days per year, at 80 percent utilization as capacity, which was developed to be an "average" amongst all types of facilities (based on copious research and analysis during the previous methodology revision). However, many hospitals provide surgery more hours per day and more days per year than the methodology assumes, putting them at a distinct disadvantage in the methodology. At the same time, ambulatory surgical facilities, which may operate fewer than nine hours per day, often fill a valuable role in improving access and enhancing value to patients needing elective surgery. The current methodology may consider them to be "underutilized," or operating at less than 80 percent of the capacity assumption; however, based on the actual hours of operation and number of surgeons performing cases, they may be more utilized than they appear to be.

The result of these differences in facilities impacts the ability of providers in need to obtain additional capacity. According to research conducted by my firm last year, freestanding ASCs in North Carolina are significantly less utilized than ORs in hospitals[1]. In essence, the current methodology considers that "all ORs are created equal," assuming that available OR capacity in a freestanding ASC can be used to meet surgical needs in a hospital, which is certainly not the case. Given the service area-wide methodology, the lower utilization of the ASCs masks the higher utilization within hospitals, preventing even those with OR utilization higher than 80 percent from obtaining additional capacity. As I noted above, however, ASCs fill a vital role in the surgical care continuum, and should not be penalized because they do not operate the same number of hours as hospitals.

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[1] See http://ascendient.com/new2015/wp-content/uploads/2015/07/NC-CON-FINAL-0722151.pdf at page 14.

3. Surgical cases performed in procedure rooms

Procedure rooms are not regulated by DHSR in licensed facilities, except to ensure they meet applicable life safety codes. Numerous surgical providers perform surgery in these rooms, which may be constructed identical to a licensed operating room. The current methodology, which is based on data from License Renewal Applications, includes only those surgical cases performed in operating rooms. Previously, from the 2008 to 2012 License Renewal Applications (FFY 2007 to 2011 data), providers were asked to report all surgical cases performed, regardless of venue, and the volume of surgical cases performed in procedure rooms did factor into need determinations generated during this time.

Based on my experience, some providers use procedure rooms to extend their surgical capacity when their operating rooms are full, but when the methodology has not allocated additional ORs. In addition, some use procedure rooms to provide patients and payors a lower-cost option within the hospital, since procedure room cases are typically billed as a bundled case, versus the separate rates for operating room time and ancillary charges. While this revision of the OR methodology will not change the regulation of procedure rooms, the revised methodology may wish to consider the following:

a. Should the methodology encourage providers to use one type of setting over the other, or remain silent on the issue?
b. If providers develop new procedure rooms to perform surgical cases that their ORs do not have capacity to accommodate, then the methodology would seem to be, in part, encouraging providers without sufficient capacity to move these cases out of ORs and into procedure rooms.
c. Should the data be presented in some way in the SMFP, perhaps like the endoscopy room inventory and volume, even if not used in the methodology?

4. Disparities in utilization among providers in the same service area

As with many of the methodologies in the SMFP that consider need at the service area level rather than by facility, the current methodology results in some providers exceeding the capacity of their operating rooms while others in the service area are well below their capacity. The revised methodology should consider that not all operating rooms are capable of providing the same cases, based on the facilities that own them. For example, capacity in an ambulatory surgical facility is not helpful to a hospital with the need for more inpatient or shared OR capacity. Even between hospitals, one may provide a higher volume of surgical

specialties that are experiencing much higher growth than others, or may provide specialties that are not provided at other facilities in the service area. Insurance and medical staff restrictions may also present barriers to the use of some operating rooms with available capacity.

While Dr. Ullrich indicated at the first workgroup meeting that a shift to a facility-based methodology may not be warranted, one alternative may be a bifurcated methodology, similar but not identical to the one used for outpatient dialysis, or the dual methodology used in the early 2000s for fixed MRI scanners (one based on mobile utilization and the other on fixed). Specifically, perhaps along with the service area-wide methodology, a facility-based methodology could be used to determine if some providers are experiencing growth that surpasses the service area growth rate. If so, a need could be generated for which anyone could apply.

5. Bases of current methodology

Among the various assumptions of the current methodology, there are several that should at least be considered for change, including:

a. Source of data

I understand the desire to move away from self-reported data to billing data collected by Truven. In my experience with Truven data for surgery, it may be necessary to have a standardized definition of "surgery" to be included in the methodology, rather than just using all cases considered "surgery" in the Truven database. I am also not aware whether Truven collects data on location of surgery (operating room versus procedure room versus bedside, etc.), if that is an important consideration in the methodology development. I understand that Truven continues to refine the way they collect data from providers, and they are certainly better able to inform us as to what is available, but I do believe the data will likely need to be analyzed and refined before it can be used for the methodology.

b. Service areas

The current methodology uses historical volume performed at licensed facilities in the service area as the base volume to which the growth factor is applied. As Dr. Ullrich mentioned at the first workgroup meeting, this does align with where patients are truly receiving care; however, it may also mask need in the patients' home county. For example, if patients do not have access to

freestanding ambulatory surgical facilities in their home county, and instead choose to travel outside the county for those services, the lack of access to the lower cost setting within their home county may not be apparent. If data were presented regarding the number or percentage of patients traveling outside the county for surgery (similar to the third prong of the linear accelerator methodology), or if an age-adjusted surgical use rate were calculated for each county compared to the state, such access issues might become more apparent.

One approach might be to allow applicants to propose developing operating rooms in or relocating operating rooms into a county in which there is no need according to the methodology, as long as the applicant can demonstrate that it currently serves patients from that county and would like to continue serving those patients in their home county.

c. Population growth rate

The current methodology projects future need for operating room capacity based on the population growth in the service area/county. While this likely assumes a high rate of surgical case growth for smaller or rural service areas, it may understate the growth in larger or urban service areas.

As discussed in #2 above, it is also likely that the growth rate between inpatient and ambulatory cases are quite different; if the projected growth rate is changed to reflect the actual historical growth in surgical cases, then separating the inpatient and ambulatory growth rates would provide an even more robust analysis of the need in the service area.

d. Chronically underutilized facilities

I support the need to define and exclude these facilities from the methodology. I would note, however, that in addition to facilities that meet the definition of "underutilized," some facilities have licensed operating rooms that are essentially "mothballed" and are not in service. If there were a method to collect this information and exclude these ORs from the inventory, it would improve the ability of the methodology to determine need.

Thank you again for the opportunity to comment. I do not expect that all of these issues can be addressed with a revised methodology, but perhaps the

discussions in the workgroup meetings will allow us to develop better recommendations going forward.

Best regards,

Daniel Carter

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