Opinions Submitted By Individual Task Force Members
In Preparation for January 9, 2017 CON Task Force Meeting

The following documents are opinions shared by individual CON Task Force members following the December 19, 2016 meeting. They include:

(1) A memo from Alan Kaye regarding recommendations related to the Acquisition of Equipment; and

(2) Voting sheets from members Robert Patricelli and Jeff Walter who cannot attend the January 9th meeting. Their votes cannot be counted in the official vote tally but are being provided to inform you of the opinions of your fellow Task Force members. These opinions will also be included in the appendix of the final report.

Memo to Members of the CON Task Force (To be submitted for the record)

From: Alan Kaye, M.D.

January 4, 2017

I had prepared a memo to send out to the Task force this evening. This afternoon, we received the draft of the report of our task force. The information presented with respect to imaging equipment confirms the need for clarification of two issues, which I present in this memo and, which, based upon the voting last month, I believe is the clear will of the Task Force. First, at our last meeting, we showed strong support for maintaining CON oversight of acquisition of imaging equipment. Nine members voted to maintain CON oversight of imaging equipment. The voting process unintentionally spread the votes to maintain CON oversight among four different options for modification. Six members voted that this aspect of CON should be eliminated, a clear minority opinion, which should not be inappropriately labeled as dominant. Nevertheless, in both instances (elimination vs. maintenance with modification), there was strong support for closing loopholes that allow self-referral – as statutory criteria if CON oversight maintained, or as a separate statute, if they are eliminated. When the Task Force was asked to weigh in on whether restrictions to self-referral should be instituted if CON oversight of imaging equipment is eliminated, all but three members voted in the affirmative.

CON oversight of acquisition of imaging equipment should be maintained. In the event, however, that it is decided that it be eliminated, however, statutory closure of self-referral loopholes must be in place if CON requirement is eliminated for acquisition of imaging equipment. This will be necessary to prevent a deluge of installations to circumvent the intent of the Task Force. The statutory linkage of the two is clearly the will of the Task Force and language to this effect should be included in our recommendations to the Governor.

Second, while there may be some confusion about the current process, the CON process should not permit replacement of imaging equipment without a CON if it is not the same type of scanner for the following reasons:

1. **It is not supported by current statute**
2. **It would be contrary to the State Health Plan**
3. **It is inconsistent with recent OHCA decisions**
4. **It will eviscerate the CON process, foster consolidation, increase the cost of care, and diminish access to care**

Discussion of second issue:

At the December 19 Task Force meeting, there was support by several members who voted to preserve CON oversight of equipment acquisitions that there be language to clarify under what

circumstances equipment could be replaced without requiring a CON. The specific language in the above-referenced recommendation is:

> *Maintain status quo and expand the current exemption applied to the replacement of scanners previously acquired through the CON process to the replacement of all equipment previously approved through the CON process, with notification to OHCA.*

Another option received no votes and reads as follows:

> *Maintain status quo and clarify that the current exemption applied to the replacement of scanners previously acquired through the CON process includes any scanner currently in operation being replaced by any other type of scanner.*

I noticed that both options specified maintaining the "status quo," but each had a seemingly different statement of what that status quo is. The one that received some support suggested expanding the current exemption for "replacement of all equipment previously approved through the CON process." The second received no support, seemingly because of the specific request for a clarification that the Task Force members deemed inappropriate.

As you may recall, I spoke against these at the meeting on December 19, with my comments addressing mostly the notion of replacing any scanner with any other type of scanner. Here is an expanded version of those comments:

> It is gratifying that most responders have expressed interest similar to that heard by you from this seat, that CON's provide many benefits in assuring cost-effective, accessible, responsible care and augment existing measures to assure quality care.
>
> CHA and several individual hospitals, including Hartford and Yale advocate that:
>
> > *The CON program should clarify that the current exemption applies to the replacement of equipment previously acquired through the CON process, including any scanner currently in operation that will be replaced by any other type of scanner.*
>
> Western Connecticut Health, Stamford, and Trinity Systems break with rest of hospitals and does not include the replacement "by any other type of scanner" provision.
>
> I am vexed by the proposal to modify the CON law whereby a scanner that had gone through the extensive justification process and met the criteria for CON ***for that particular type of scanner and service*** would be allowed to be replaced with "any other type of imaging equipment," even one that has a completely different medical use, different cost and different reimbursement - i.e., with completely different clinical and business cases which may have zero relevance to the criteria for which the original CON was granted.

This would be a drastic change from current policy. In fact, it is antithetical to the whole concept of a set of criteria to be considered for a CON. For example, that would mean that an operator of a PET scanner (primarily a cancer detection, staging, and monitoring tool) could decide that it is not profitable or it is not meeting the need that it stated to be the case in its application and replace it with a MRI scanner because it has a much better profitability, even though it is a completely different technology with a different set of medical uses. A provider could take any number of unprofitable scanners and replace them with a completely different fleet of scanners.

Even more perversely, a shrewd applicant could apply for and justify one type of scanner, gain OHCA approval for a CON, and shortly thereafter replace it with another scanner (again, with a completely different business and use cases). This could even be a premeditated action.

Surely, the above scenarios or others like them should not be enabled by these proposed modifications. If the "any other type" language is adopted, or if the "status quo" is "expanded," it would allow providers to circumvent the process by which OHCA determines the need for, and impact of, a particular type of equipment in a given service area - in effect, eviscerating the CON process and voiding all the hard work done in the past by OHCA and DPH in CON rulings.

Interestingly, the specific wording of the hospitals' submissions is identical in many respects. What is interesting is that some of the hospitals did not include this seemingly inexplicable interchangeability of different types of scanners. At first, I did not understand why hospitals would, on the one hand, submit comments lauding the CON process and on the other would espouse something so antithetical to the principle of CON. Perhaps the rationale is to exploit the extensive consolidation of services that has occurred in certain hospital systems. (Indeed, one of the precipitating events leading to the Task Force's formation was closure of services in an outlying community and moving them to a more central, larger venue.)

In the specific case of imaging equipment, it may be more profitable to close down certain services – e.g., PET-CT – at some smaller hospitals of a large system and move those patients to a central facility. While that might be advisable, there is no reason to "grandfather" the Certificate of Need for a completely different type of scanner that may, in all likelihood, be moved to anywhere in the state that the System wishes, and without the oversight that a CON process provides, a process which almost all submissions support in principle. To make this even more concrete, let's say a hospital system now has 5 or 6 hospitals. There may be 25 or more pieces of equipment that have Certificates of Need. This would include 5 or 6 PET (or PET-CT) scanners, acquired at a time when they were independent. If this language is adopted, then, without any oversight, the System could replace 4 PET with MRI scanners move them anywhere in the state, without oversight as to need, access, cost of care, etc. Furthermore, it would

stifle the competition that some on this task force have espoused, lead to higher prices because they are hospital machines, and be anything but the "level playing field" that the hospitals themselves espouse.

Because of the incongruity of the two proposals submitted with respect to the "status quo" I sought clarification from OHCA staff. Staff is under the impression that replacements can occur for "any other type of scanner." This is a huge surprise to me, as I have been a keen observer of the CON statutes and served on the most recent OHCA committee on drafting CON guidelines and regulations. Moreover, this is not supported by current statute; it is contrary to the State Health Plan; and it is not consistent with recent OHCA decisions.

Some historical background on this issue of replacement of imaging equipment with "any other type of scanner":

1. It is not supported by current statute (thereby depriving the public and the legislature of weighing in on this very important issue with significant potential impact on patient care, access to services, and cost of care):

Historically, OHCA had been operating under statute passed in 2010 (**P.A. 10-179)** https://www.cga.ct.gov/2010/ACT/Pa/pdf/2010PA-00179-R00SB-00494-PA.pdf.

This was part of the initial overhaul of the CON statutes in 2010. Section 19a-638 was divided into two sections: Section "a" lists what does require a CON and Section "b" lists what does not require a CON.

Section 19a-638(a)(8) of the CGS was revised by P.A. 10-179 to state as follows:

> *(a) A certificate of need issued by the office shall be required for ... (8) The acquisition of computed tomography scanners, magnetic resonance imaging scanners, positron emission tomography scanners or positron emission tomography-computed tomography scanners, by any person, physician, provider, short-term acute care general hospital or children's hospital;*

In addition, Section 19a-638(b)(18) of the CGS was revised by P.A. 10-179 to state as follows, whereby scanners obtained through the CON or determination process could be replaced without CON:

> *(b) A certificate of need shall not be required for ... (18) Replacement of existing imaging equipment if such equipment was acquired through certificate of need approval or a certificate of need determination, provided a health care facility, provider, physician or person notifies the office of the date on which the equipment is replaced and the disposition of the replaced equipment;*

In 2015, P.A. 15-146 added replacement language similar to that found in Section 19a-638(b)(18) into Section 19a-638(a)(10), thereby duplicating the replacement provision that has existed in the CON statutes since 2010. With passage of P.A. 15-146, Section 19a-638(a)(10) (formerly 19a-638(a)(8) as referenced above) reads as follows:

> *(10) The acquisition of computed tomography scanners, magnetic resonance imaging scanners, positron emission tomography scanners or positron emission tomography-computed tomography scanners, by any person, physician, provider, short-term acute care general hospital or children's hospital, except (A) as provided for in subdivision (22) of subsection (b) of this section, and (B) a certificate of need issued by the office shall not be required where such scanner is a replacement for a scanner that was previously acquired through certificate of need approval or a certificate of need determination;*
>
> https://www.cga.ct.gov/2015/ACT/PA/2015PA-00146-R00SB-00811-PA.htm

In the 2016 legislative session, Raised Bills 5451 and 289 included proposed changes to Section 19a-638 of the General Statutes, and in particular the subsections concerning replacement of major imaging equipment. RB 5451 proposed to exempt from CON the replacement of any CT, MRI, PET, or PET-CT with "any other type of imaging equipment." RB 289 proposed to allow for replacement of any CT, MRI, PET, or PET-CT with "a combination scanner that has additional capabilities and modalities" without CON approval.

The Radiological Society of Connecticut was very concerned about RB 5451 for the reasons stated above and drafted testimony on the bill stating its opposition to that language. RSC did not have to submit this testimony, because the Governor announced a moratorium and formed this Task Force, which would deal with CON-related issues like this. Thus, no new language regarding CON replacement was passed in the 2016 session, and the language in P.A. 15-146 remains unchanged.

2. It is contrary to the State Health Plan:

Section 5.3 says: "Under current law, any previously authorized imaging scanner ... can be replaced with a similar scanner (e.g., a 1.5T MRI scanner with a 3.0 MRI scanner, or a 4-slice CT scanner with a 16-slice CT scanner) ...".
http://www.ct.gov/dph/lib/dph/ohca/hc_facilities_advisory_body/ohcastatewide_facilities_and_services_chapter_5_imaging_and_new_technology.pdf

3. It is inconsistent with recent OHCA decisions:

PET-CT determination issued to Advanced Radiology Consultants from October 2014. Note on the second to last page: "The PET-CT that the Petitioner is seeking to acquire is not a direct replacement of the current PET scanner. Therefore, the Petitioner's proposal is an acquisition

of imaging equipment rather than a replacement and a CON is required."
http://www.ct.gov/dph/lib/dph/ohca/condeterminations/determinations_2014/14_31951_dtr.pdf

Proposal:

That the Task Force clarify the current process and recommend:

1. MRI, CT, and PET scanners initially acquired in accordance with the law be upgraded without CON approval, provided that the replacement is the same type of scanner or, in the case of PET scanners, allow replacement with PET-CT. (Providers must be able to replace major imaging equipment with state-of-the-art technology. PET-CT is now the standard of care, where it once was PET. PET-only scanners are no longer produced for clinical use. So a provider who wants to upgrade a PET scanner should be allowed to acquire a PET-CT without CON approval, affording its patients the highest standard of care.)
2. Prior to or simultaneous with any repeal of or substantive change to CON requirement for acquisition of imaging equipment there should be in place language that mirrors the Federal Stark Laws' prohibition of self-referral, but applies to all payers and removes the in-office ancillary services exception for MRI, CT, and PET/PET-CT.

Respectfully Submitted,

Alan Kaye, M.D.

From: Patricelli, Robert <Rpatricelli@womenshealthusa.com>
Sent: Wednesday, December 21, 2016 3:27:20 PM
To: Foley, Anne
Subject: Remaining CON Decisions

Anne:
As you know I will not be able to attend, either in person or by phone, the final meeting of the Task Force in January. Therefore, with your encouragement, I am submitting my voting preferences on the remaining decision items, regretting that I don't have the benefit of the always enlightening comments of my colleagues on the panel. Please feel free to distribute them as you see fit.

#4. Initiating services, increasing capacity. I would prefer to do away with CON review altogether on these matters, on the ground that we already have considerable consolidation in CT and need more, not less, competition. CON in these instances becomes a means by which existing competitors can try to obstruct new entrants. Let the market work. If doing away with CON in these instances is not possible, I would vote for 4A.

#5. Vote for A.

#6. Vote for A.

#7. Vote for B plus C.

#8. Vote for C.

#9. Vote for A.

#10. Vote for A.

#11. Vote for A.

#12. Vote for A.

#13. Leave as Status Quo (not an available option?)

#14. Vote for A.

#15. Leave as Status Quo.

#16. Vote for A, B and C.

#17. A—yes; B—yes; C—no; D—yes; E—yes; F—yes.

#18. Vote No on all points.

It has been an honor and privilege to serve with you, the other members of the panel, and the Lt. Governor. Best regards,

Bob Patricelli

Robert Patricelli
Chairman and CEO, Women's Health USA
whusa

Jeff Walter's Scoring Sheet -

1. Transfer of Ownership	A
2. Conversions	A
3. Acquiring Equipment	D
4. Initiating/Expanding	E
5. Terminations	B
6. Service Reductions	C
7. Relocations	B
8. DSS	A
9. Application Review-Acquisitions	A
10. Application Review- Terminati	A
11. Applicatation Review-Transfer	A
12A. Organization	No
12B. Organization	No
12.C Organization	No
13A. Public	No
13B. Public	Yes
13C. Public	Yes
14A. Appeals	Yes
14B. Appeals	Yes
15A. Transparency	Yes
15B. Transparency	Yes
16A. Process	Yes
16B. Process	Yes
16C. Process	No
17A. Compliance	Yes
17B. Compliance	Yes
17C. Compliance	No
17D. Compliance	Yes
17E. Compliance	Yes
17F Compliance	Yes
18A. Evaluation	Yes
18B. Evaluation	Yes
18C. Evaluation	Yes

Maintain existing exemption process for SUD and MH facilities