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RE: CON for Angioplasty without Cardiovascular Surgery Standby

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Sun, Oct 11, 2009 at 10:17 PM

To: "Banahan, Carrie (CHFS Office of Health Policy)" <carrie.banahan@ky.gov>

Cc: "Burch, Tom (State Rep.) (LRC)" <Tom.Burch@lrc.ky.gov>

Ms Banahan,

I was asked to review the new CON regulations and have a few comments. Keep in mind that I feel the CON usefulness is questionable and much of these changes could also handled under licensure requirements.

Of concern were the provisions granting angioplasty CONs in facilities without cardiovascular surgery. At first, I noted that this was a non-substantive review but on further study it appears this is only for programs that have successfully completed the pilot project. The requirements set in the regulations appear to be well thought out but one should seriously consider adding another (see end of e-mail).

As you know the indications for angioplasty are rapidly changing with some experts estimating 20% to 30% of cases might be better handled by medical therapy alone. Thus, in all likelihood the number of angioplasties in the future will be expected to drop.

http://www.businessweek.com/technology/content/jun2009/tc2009065_436591.htm

The New England Journal of Medicine reported that patients with Type 2 diabetes and heart disease did not benefit from angioplasty and stent placement.

<http://content.nejm.org/cgi/content/full/NEJMoa0805796>

The placement of coronary artery stents as an initial management of stable coronary artery

disease did not reduce the incidence of death or heart attack when added to medical therapy.

<http://content.nejm.org/cgi/content/short/356/15/1503>

A recent article in the March 5th edition of the NEJM found that Coronary-Artery Bypass Grafting was more effective than percutaneous coronary intervention with drug-eluting stents

for the treatment of severe coronary artery disease.

<http://content.nejm.org/cgi/reprint/360/10/961.pdf>

Authors Mark, et al., found in the treatment of late myocardial infarcts (heart attacks), no difference between medical therapy and percutaneous coronary artery intervention (stents).

<http://content.nejm.org/cgi/content/abstract/360/8/774>

The controversy of elective angioplasties performed without cardiovascular surgery standby is that there has been a significant increase in mortality rate, almost 30% -- JAMA Oct 27, 2004. <http://www.ncbi.nlm.nih.gov/pubmed/15507581>

This must be weighted by the marked increase in restoration of blood flow in heart attack victims for angioplasty compared to medical treatment or with the use of clot busters. <http://www.ncbi.nlm.nih.gov/sites/entrez/17293178>
<http://www.ncbi.nlm.nih.gov/pubmed/10347347>

And for angioplasty to improve outcomes in acute myocardial infarctions the cardiologist must be skilled and the facility experienced at procedure performance. In facilities with less than or equal to 16 there was no treatment difference, see figure in the below reference. <http://jama.ama-assn.org/cgi/reprint/284/24/3131>

Since the cardiologist must be skilled at doing angioplasties, he must also be allowed to do elective angioplasties if he is expected to have good outcomes at emergency angioplasty for acute myocardial infarction.

Thus, I would encourage the State to restrict approval of facilities allowed to perform elective and emergency angioplasties without cardiovascular surgery standby to communities that do not have cardiovascular programs or where such programs are not readily available and to carefully weigh risks versus benefits before granting approval.

I would also seriously consider adding the requirement that "An applicant document and perform over 16 angioplasties per year for the treatment of acute myocardial infarctions." since according to Magid, et al (JAMA, Dec 27, 2000 <http://jama.ama-assn.org/cgi/reprint/284/24/3131>) this would be the minimum for a beneficial effect to be observed from granting such a CON. Elective angioplasties otherwise are more safely performed in a setting with cardiovascular surgery standby.

Thank you for this consideration,

Kevin T Kavanagh, MD, FACS