New Certificate of Need Regulations Proposed in Alaska

Legal Alert
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Garvey Schubert Barer Legal Update, August 4, 2009.

On July 15, 2009, the Department of Health and Social Services for the State of Alaska proposed new regulations. While many of the proposed regulations, if passed, will have a mundane impact on the Certificate of Need (CON) process, there are a few proposed regulations that will have a pronounced impact.

Independent Diagnostic Testing Facility

Since the Department first adopted a definition for independent diagnostic and testing facilities (IDTF) in 2006, delineating what constitutes a "doctor's office" and therefore not subject to CON laws and what constitutes an IDTF and therefore subject to CON requirements has bee problematic. At least one case reached the Alaska Supreme Court seeking guidance on what constituted an IDTF. See, *Bridges v. Banner Health*, 201 P.3d 484 (Alaska 2008).

The current definition of an IDTF found at 7 AAC 07.012 relies upon a reference to federal law to define what constitutes an IDTF. Under the proposed regulations an IDTF would now be defined as an "outpatient facility" that is "designed and equipped solely to perform diagnostic testing using major diagnostic testing equipment for an independent diagnostic purpose" and "is **not** owned by any other health care facility [;] or an office of private physicians or dentists exempt from" the CON process. The proposed regulation containing the definition of an IDTF is at proposed 7 AAC 07.900 (24).

While the further refined definition of an IDTF in the proposed regulations will eliminate some of the definitional problems it remains to be seen whether this new definition will help eliminate the spate of CON appeals this definition has caused.

The One Who Files Their CON Application First Gets an Advantage

Under the current regulations, a provider files its CON application with the Department. Once this CON application is filed, the Department issues a notice stating that the CON application has been filed and allows for competing CON applications to then be filed. If one or more additional CON applications are filed the Department then analyzes each application and advises the Commissioner who they believe should be awarded the CON. The applications are treated as though they were filed at the same time. In many situations, the healthcare providers are fairly evenly matched and propose to provide the same type, level, and quality of healthcare service. Should the Department believe that the providers were equally capable,

there is no mechanism for determining which one should be awarded the CON. In some instances it was possible to split the project so that both requesting providers could meet the healthcare need identified. However, in many instances a choice had to be made.

To address this situation the proposed regulations at 7 AAC 07.060 (c) now state that if two or more competing providers are determined to be "equally capable" a preference shall be given to the provider who first filed the CON application.

As a practical matter this means that if your organization files its CON application second or in response to another healthcare provider's CON application, your organization will be at a significant disadvantage. If you are the second or later filing entity, not only do you have to meet all of the usual requirements imposed by the CON laws, you will also have to prove that your CON proposal demonstrates that your organization is more capable than whatever organization filed first in order to be awarded the CON. Showing that your organization is equal to the organization that first filed will result in the other organization being awarded the CON. Significantly, it appears that even under circumstances where the Department would be able to split up one large project so that two separate organizations could provide the healthcare service that will no longer be an option as the regulation appears to command the Department to choose one organization to award the CON to.

New Limitations on What Evidence Can Be Presented on Appeal

Under the current regulations once the Commissioner awards a CON or denies a CON, the organization opposing the Commissioner's action may file an appeal which is heard by an administrative law judge (ALJ). Under current law the appeal hearing is considered *de novo* which means that both parties can present whatever evidence they would like.

Proposed 7 AAC 07.080 seeks to limit what evidence can be presented to the ALJ on appeal. If adopted, this proposed regulation would limit the evidence that the ALJ could consider to just "the record that existed at the time of the [Commissioner's] decision." There is a provision for submitting some additional evidence but the proponent wanting to submit the new evidence must establish "good cause" for allowing the new information into evidence. Among other things the regulation states that one can meet this difficult "good cause" standard if they can show that the evidence "was available to the department during the application and decision process" and "was not considered or was improperly considered or that evidence which was unknown at the time of the decision is now available."

If one cannot establish "good cause" for allowing new evidence into the record on appeal, the record will be limited to the CON application, the statements made at the public hearing, the written statements received by the Department during the comment period, and any other information found by the CON staff. While most would agree that the appeal process should be streamlined it is not clear that limiting evidence is the proper way to do this. The record on appeal will include the statements made at the public hearing and the written comments made

during the comment period. The problem is, none of these statements, oral or written, are made under oath. Oftentimes statements are provided to the Department with little or no factual support and no one is ever required to make their statement under oath. Further, none of the statements are tested by allowing someone to question the person making the statement.

Since no one is required to make their statement under oath or attest to its accuracy it is quite possible that the record on appeal will be riddled with incomplete or inaccurate "facts." Those opposed to the CON applicant (as well as the CON applicant) will have to do their best to put in as many facts as they can during the public hearing process and written comment time period so that they will have a factual basis on which to base their opposition on appeal. Failure to include these salient facts in the record prior to the Commissioner making the decision on whether to issue a CON could be fatal to any attempt at a subsequent appeal.

If this change in regulations is adopted it will be critical to create your record very early in the CON process. CON applicants and opponents will want to have all of their facts in the record prior to the Commissioner issuing the CON decision. CON applicants and opponents should consider filing sworn statements such as an affidavit with the Department. Affidavits are not required but on appeal it may be helpful to direct the ALJ's attention to one's own sworn statements that are in the record.

Conclusion

For most healthcare providers the proposed change in what evidence will be allowed on appeal is the most significant change in the proposed CON regulations. A copy of the proposed regulations can be found at:

www.hss.state.ak.us/dph/healthplanning/cert_of_need

If you wish to comment on the proposed regulations you must do so by 5:00 p.m. on October 15, 2009. Written comments should be directed to: Kevin Henderson, Office of the Commissioner, P.O. Box 110601, Juneau, AK 99811-0601; kevin.henderson@alaska.gov.