



North Carolina Certificate of Need - Landscape for the Remainder of 2021

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Predictably, the 2021 Certificate of Need (CON) year in North Carolina has begun with a veritable flurry of activity ? what has happened to date and, importantly, what we can expect for the remainder of the 2021 CON year?

On the Horizon

While not an exhaustive list of what lies ahead, several notable opportunities are forecasted for the balance of 2021.

Operating Rooms

Opportunities abound for new proposals for Operating Rooms (ORs) in key North Carolina markets. ORs can be proposed by new market entrants or by existing Surgery Centers or Hospitals. Three ORs are shown as needed in Orange County with applications due in June. Three ORs are shown as a need in Wake County with applications due in August. Finally, two ORs are identified as a need in Brunswick County with applications due in October.

MRI Scanners

Proposals for a new MRI scanner will be accepted for Mecklenburg County in August, for New Hanover County in September, and for Orange County in October.

PET Scanners

Several key opportunities remain for providers seeking approval for new PET scanners. Proposals will be accepted in June for Health Service Area IV, which consists of a number of counties including Orange, Wake and Durham. Proposals are due in September for the large Health Service Area VI which includes Pitt County and a range of other Counties. Applications will be received in October proposing PET capacity in Health Service Area V which encompasses multiple Counties including New Hanover County. In October, the State will receive applications for Statewide mobile PET proposals.

Other Health Care Capacities

Providers can apply for CON approval to develop various numbers of new acute care beds in locations across the State (Cabarrus, 22 beds in August; Mecklenburg, 123 beds in October; and New Hanover, 35 beds in June).

In a range of mostly rural counties, several more 2021 proposals will be accepted for the development of new Adult Care Home beds, commonly referred to as assisted living beds. Some of the Need Determinations are for a low number of beds but a few are of sufficient size to potentially support a stand-alone facility.

The Governor included an adjusted need determination for 70 adult substance use disorder beds in the Eastern Region with applications due in mid-May. A few psychiatric bed filing opportunities remain in 2021, as well as a few openings to apply for substance abuse disorder beds in various areas of the State. As noted below, despite opportunities, only one psychiatric bed proposal ? a relocation ? has been submitted thus far in 2021.

Early 2021 CON Activity

The 2021 bustle of activity in CON has included a range of project proposals submitted during the early months of the calendar year, highlights of which include the following:

Most recently, the Agency received a \$31 million renovation proposal from a provider in Alamance County. In Buncombe County, two competing CON Applications were submitted in response to the Need Determination for a new PET scanner for Western North Carolina. Also, in Buncombe County, a long-term care provider has proposed a bed relocation project. Earlier this year, three competing MRI projects were proposed in response to the 2021 Need Determination for a new scanner in Buncombe County.

Earlier this year, a provider proposed a new 40-bed hospital in Wake County. In turn, its competitor recently filed a proposal for a new 40-bed hospital in Durham County. Several applicants will vie for the approval of new operating rooms in Durham County.

In the most recent burst of CON activity, multiple providers will compete for the single Home Health Agency approval for Mecklenburg County. In Orange County, applications were received for a diagnostic center project and for an expansion of a hospital-based oncology clinic. Applications were recently received from several providers seeking to develop diagnostic centers and acquire MRI capacity in Wake County.

Two Haywood County assisted living project proposals were submitted in 2021. Alamance County was the site for a 2021 proposal for a new diagnostic center. A linear accelerator replacement was proposed in Onslow County, and a GI center relocation proposal was submitted by a Union County provider.

Several Cost Overrun CON Applications were filed early in 2021 by providers operating in Union and Mecklenburg Counties; also, for Mecklenburg County, a nursing home relocation proposal was

submitted.

A new freestanding hospice inpatient facility was proposed for development in Watauga County. Dialysis projects are a mainstay in the CON arena. Apart from the typical array of dialysis projects, a psychiatric bed relocation project proposal was also proposed in early 2021.

A new da Vinci Xi Robotics System was proposed for location in Catawba County. A Cumberland County provider filed a Change of Scope application proposing the addition of a surgical specialty to its existing center. Finally, a new diagnostic center was proposed for development in Durham County.

The most recently filed Applications will be a part of Reviews commencing at the start of May, with competitive comments received during the initial 30 days of the Review period.

CON Cases Arising from 2020 Reviews

A discussion of the CON landscape would not be complete without a review of pending matters which remain in play following earlier CON reviews. Various Administrative Law Judges (ALJs) are handling cases arising from 2020 CON decisions:

- Judge May is the Administrative Law Judge assigned to the ongoing litigation at the Office of Administrative Hearings (OAH) arising from the 2020 need determination for two additional ORs in Forsyth County;
- Judge May is also presiding over a matter involving denial of a CON for an assisted living facility relocation project in Moore County;
- Judge Ward is the presiding Administrative Law Judge in the consolidated matters involving MRI scanner capacity for Wake County; and
- Judge Bryne is assigned to the contested case over a proposal for a new satellite hospital campus in Mecklenburg County.

In addition, several new CON cases have been filed this calendar year. Highlights include:

- An existing operator of a diagnostic imaging center filed to challenge the approval of a new diagnostic center in Orange County.
- Challenges by several applicants were initiated following the Agency decision in the Wake County operating room review.
- Two denied applicants filed to challenge the Agency's decision in the Rowan County hospice review.
- An applicant that had been denied in its bid for CON approval for a new Surgery Center in Iredell County filed a contested case.
- A contested case was filed following the denial of a proposed hospital project in New Hanover

County.

- Another CON case was initiated by existing providers following the Agency approval of a GI endoscopy facility in Granville County.

With no CON case filing to challenge the Agency decision, a CON is now expected to issue allowing for a new Fixed MRI scanner project in Guilford County.

And while a CON law challenge remains pending in Wake County, at the General Assembly several pieces of ?perennial? proposed legislation have surfaced ranging from proposals to modify the CON law to bolder proposals to eliminate CON regulation across the State. The latest CON legislative proposal would allow physician groups to acquire MRI capacity without CON approval under specified terms. In addition, industry observers are keeping a keen eye on the on-going progress of the various committees who work each year to support development of North Carolina?s State Medical Facilities Plan. Meetings are in full swing including both typical and novel meetings designed to consider appropriate content for the first State Plan to follow a world-wide pandemic.

The year 2021 includes open CON opportunities and a range of filed and contested proposals, as well as ongoing planning and legislative initiatives. The year promises to yield interesting decisions that will shape the development of health care capabilities in various areas of North Carolina.

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