Section 7

Summary of Public Comments

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Office of Health Care Access Administrative Regulations
Sections 19a-613-1 through 19a-653-4 of the Regulations of Connecticut State Agencies

SUBJECT: Proposed regulations necessary to administer the Certificate of Need process under Public Act 10-179 §§ 87, 89-93.

COMMENTERS: **James Iacobellis**, Vice President, Government Relations, Connecticut Hospital Association

NUMBER OF COMMENTERS	COMMENT	RESPONSE
1	There is a typographical numbering error in subsection 19a-630-1(2). The last clause reads "…and satisfying the criteria for a central service facility as discussed in section II, below;" The reference to "Section II" is incorrect, and should read: "…and satisfying the criteria for a central service facility as discussed in section 19a-630-2;"	The error has been corrected in the revised regulations
1	The definition of central service facility incorporates much of the existing definition, but slightly alters certain clauses in a manner that could result in an unforeseen negative consequence to the state. Specifically, the *existing* definition of central service facility found at 19a-643-12(4) states that an entity is considered a central service facility if it is: "…one or more partnerships or corporations beyond a group of practicing physicians whose practice this is or will be, who will control a business involving health services." The proposed change, found in Section 19a-630-2(a)(4), departs from current law in that it removes oversight of non-physician owned business entities as potential central service facilities. During the comment period for interim policies and procedures, a commenter requested DPH make this change. We disagree with that prior commenter, and emphasize that this removal will create a hole in the framework of CON that could result in an immediate	We revised the regulations accordingly.

	influx of unregulated corporate-based or non-physician owned services entering the market. CHA respectfully requests that the original regulation's language be retained.	
1	**19a-638-3**. Determinations. Public Act 10-179 ("Act") revised section 19a-638 of the General Statutes, and indicates that the determination process is started when an applicant sends a "letter." This proposed regulation indicates that the applicant must use a "determination form." CHA is concerned that the difference in terms between the statutory language and the proposed regulation may cause confusion. We respectfully request that DPH clarify in regulation that the "form" will substitute as the "letter" described in statute.	It is not necessary to provide further language indicating that the form will substitute as the letter. OHCA has always received determinations on the determination form and has also accepted determinations in letter format. Additionally, a letter typically accompanies the form.
1	**19a-639a-2**. Newspapers with substantial circulation. As we have noted in prior comments to proposed DPH policies and procedures, we urge DPH to have a regulation that accepts all newspapers of substantial circulation, not just the perceived major news publication in an area.	As stated in the past, OHCA is using the list followed by other state agencies and if anyone would like to add certain newspapers to the list they should feel free to do so.
1	**19a-639a-3(a)(4)**. The text of this proposed regulation states: "(4) A detailed description of how the proposal satisfies each of the guidelines and principles enumerated in section 19a-639 of the general statutes and any supporting documentation;" The Act, however, does not require adherence or satisfaction of each of the elements in the guidelines and principles, only "consideration" of each by the Office of Health Care Access (the "Office"). Section 19a-639 of the General Statutes, as amended by the Act, states: "the office must take into consideration and make written findings concerning each of the following guidelines and principles." The proposed regulation alters the Act's meaning, implying (if not stating) that an applicant must "satisfy" each of the guidelines and principles. This is not	The change has been made.

	legally correct, and is beyond the parameters of the Act. This section exceeds the Act's mandate, which is directed to the Office, for reference to, and compliance with, the principles and guidelines set forth in the statutory scheme. We respectfully request that the following changes be made to proposed section 19a-639a-3(a)(4): "(4) A detailed description of how the proposal relates to [satisfies] each of the guidelines and principles enumerated in section 19a-639 of the general statutes and any supporting documentation;"	
1	**19a-639a-5(a).** To gain clarity regarding which review periods are being discussed, the proposed regulation should be revised as follows (inserted language is underlined): "(a) The 90-day review period for a completed application will begin on the date on which the office publishes notice on its website that the application is complete pursuant to [with] subsection (d) of section 19a-639a of the general statutes. The office shall publish notice on its website as expeditiously as possible and in no instance more than seven days beyond the expiration of the thirty day review period that the application is deemed complete. Additionally, the office shall provide notice that the application is complete to the applicant via first class mail, facsimile or electronic mail. The notice to the applicant shall also notify the applicant of the date on which the 90-day review period expires. The notice on the website shall serve as notice to any interested members of the public."	We have revised the language in an effort to provide more clarity.
1	**19a-639b-1**. Voidance of Extension of Certificate of Need.	We have removed the terms void and voidance from the regulation.

	The term "voidance" and "void" do not appear in the Act or in prior CON regulations. The Act references the timeframe during which a CON is "valid." CHA is concerned that introducing the term "voidance" and "void" may lead to unforeseen legal issues and challenges as these terms carry the potential legal consequence of invalidating the CON *ab initio*, which is not contemplated by the Act. We suggest that the terms "voidance" and "void" be replaced with "invalidation" and "invalid" to conform to the language of the Act.	Instead, we state that the CON will expire after two years.
1	**19a-639c-3**. Certificate of Need for Relocation. This section could be read to mean that all applicants seeking relocation must first attempt to demonstrate that there will be no substantial change in payer mix or patient population. That step may be entirely unwarranted in many cases where the applicant does not claim, or represent, that no substantial changes will result. We respectfully request that the office clarify that an applicant may simply state that it does not intend to claim no substantial changes will occur, and go directly to the full CON process. This could be accomplished by the following revisions (inserted language is underlined): Section 19a-639c-3. Certificate of Need for Relocation Any health care facility that proposes to relocate its facility and is unable to demonstrate <u>(or does not wish to attempt to demonstrate)</u> to the satisfaction of the office that the relocation will not result in a substantial change in the payer mix or population served shall file a certificate of need for the establishment of a new health care facility pursuant to subdivision (1) of subsection (a) of section 19a-638 of the general statutes.	We have revised the language.