Rhode Island Department of Health

Public Hearing RE:
Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Care Services

Rhode Island Department of Health
3 Capitol Hill
Providence, RI 02908
September 7, 2018
10:25AM

Before: Sullivan Roberts, Hearing Officer

Exhibits:

1. Notice of Proposed Rulemaking
2. Proposed Regulations
3. Existing Rules and Regulations
4. R.I. Gen. Laws §§ 23-15-4(g) and 23-15-5(a)
5. Office of Regulatory Reform Authorization Email

(Commenced at 10:25AM)

Hearing Officer Roberts: Welcome. We are here today to conduct a public hearing concerning the rules and regulations for Determination of Need for New Health Care Equipment and New Institutional Health Care Services. This hearing is being conducted under the provisions of Rhode Island General Laws 23-17 and 42-35. Today is Friday, September 7th, 2018. My name is Sullivan Roberts, Rules Coordinator for the Rhode Island Department of Health, also known as RIDOH, and I will be the hearing officer for today's proceeding. This is Michael Dexter, Chief of the Center for Health Systems Policy & Regulations. And this is Morgan Enroth, Health Economics Specialist for the Office of Health Systems Development.

Before we start, and to prevent any interruption of the proceedings, at this time I would like to ask those of you with cell phones, pagers, and watch alarms to turn them off, or set them to silent or vibrate.

The purpose of the hearing today is to afford interested parties an opportunity to comment on the proposed regulations, allow as many people as possible to be heard, and to ensure that an accurate record of all comments is obtained. This hearing is intended for your participation only, and is not intended to provide a forum for discussing, debating, arguing, or otherwise having dialogue on the regulations before us with RIDOH personnel as part of this public hearing.

If you would like to speak, the procedure we will use is as follows:

Please register to speak at the rear of the room. Speakers will be taken in order of registration. Up to five minutes will be allowed for your presentation unless the lack of speakers allows for additional time. If you are reading off a prepared document, such as a paper copy or electronic version of your testimony, we politely request that you speak clearly and at an unhurried pace. I will indicate when you have one minute of time remaining. If you are unable to complete your testimony in the time allotted, you may have an opportunity to speak if any time is remaining after the other speakers who have signed up complete their testimony.

When you are called, come to the podium. Identify yourself by name and affiliation, if any. Please spell your name and give the full name of your organization if you used an acronym (such as NASA). Make your presentation and make sure to conclude within the allotted time of five minutes. If you have a written copy of your statement, we would appreciate if you could provide it for the record. If you read from an electronic version of your testimony, we would appreciate if you could provide a hard copy or email us your testimony.

In accordance with the requirements of the Administrative Procedures Act, additional written comments on these proposed amendments will be accepted by Monday, September 17th, 2018.

After the conclusion of the public comment period, RIDOH has four options under state law: The first option is to file the regulations as posted with the Secretary of State. The second option is to file with minor technical changes such as correcting spelling; punctuation; etc. The third option is to make non-technical changes in what you see before you today which would be addressed in RIDOH's Concise Explanatory Statement filed with the final regulations, and could also necessitate a new public hearing and associated public notice posting. And The fourth option is to not file the proposed regulations, in which case, the current regulations would remain in effect. Unless otherwise specified by law, regulation, or at the discretion of RIDOH, once filed, the regulations become effective twenty (20) days after filing and have the force of law upon that date.

Are there any questions on how the public hearing will be conducted today?

(PAUSE)

Hearing Officer Roberts: At this time, for the record, we will have a presentation of exhibits:

The first exhibit is the notice of proposed rule-making posted on the Rhode Island Secretary of State's website on August 16th, 2018.

The second exhibit is a copy of the proposed regulations with revisions indicated, also posted to the Rhode Island Secretary of State's website on August 16th, 2018.

The third exhibit is a copy of the existing Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services, last filed with the Rhode Island Secretary of State in January 2017.

The fourth exhibit is a copy of Rhode Island General Laws sections 23-15-4(g) and 23-15-5(a), the enabling statutes for these regulations.

The fifth and final exhibit is a copy of the e-mail dated August 10th, 2018 from the Office of Regulatory Reform to Sullivan Roberts confirming that RIDOH was authorized to move forward with promulgation of these regulations.

At this time, I would like to call the first speaker, Jodi Bourque.

Ms. Bourque: Jodi Bourque, J-O-D-I B-O-U-R-Q-U-E, I represent Lifespan Corporation. I'm the associate general counsel there. I have three minor comments, we're going to be limiting our comments to just the changes and not the philosophy with regard to CON, so they're just minor with regard to the changes requested.

The first one is in section 22.10, the language regarding bundling similar CONs is being removed, and we would request that language not be removed in the eventuality or just sort of a strange scenario that there'd be a cycle where there would be two CONs for the same thing, in which only one would be awarded. You know, in the eventuality that that would happen it could be theoretically possible that the first one that was filed could be approved, thereby knocking out need for the second one and we think those should be bundled and reviewed together if there was ever a situation where there were competing CONs.

With regard to section 22.11, it states that the public meeting will be before the Department instead of the Health Services Council that's the requested change, and we feel that the public meeting should be before the Health Services Council because they are the decision maker and it's a completely different feel, from somebody who's sat through public meetings before and listened to live testimony, to be at a public meeting and listen to testimony versus reading a transcript after. I also personally feel that it will be more efficient because what will likely happen is people will come to the public meeting, testify before the Department and then they'll also still just show up at Health Services Council and say the same thing, so I think having it before the Health Services Council makes sense on both of those reasons.

22.17, the language allowing for a public meeting for a motion for reconsideration was removed. While we don't think that a public meeting for a motion for reconsideration should be required, it removed all language with regarding public process for a motion to consideration, and the problem with that could be that if it was a motion for reconsideration from an affected party, theoretically the applicant wouldn't even know about it if there's no notice provisions with regard to motions for reconsideration. So we feel that at the minimum, a motion for reconsideration should be noticed to affected parties. Thank you.

Hearing Officer Roberts: Thank you. The next speaker is Adelita Orefice.

Ms. Orefice: Thank you. My name is Adelita Orefice, I we represent a variety of clients basically here from Barrett and Single, an attorney with Barrett and Single. I have comments on a just a particular section. Section-

(FIRE ALARM SOUNDS)

Hearing Officer Roberts: We're taking a recess for the fire drill, we will return.

(RECESS FOR FIRE EVACUATION)

Hearing Officer Roberts: Sorry for the interruption, we're going to kick this off again. So the next speaker is Adelita Orefice.

Ms. Orefice: Hi my name is Adelita, A-D-E-L-I-T-A, last name is Orefice, O-R-E-F as in Frank I-C-E. I'm an attorney with Barrett and Single. I'm just going to comment today on one section of the regulations, that's section 22.7 Review of Nonclinical Capital Expenditures which was revised to reference the statute. And it essentially that section references the definition of nonclinical proposal to mean any capital expenditure by or on behalf of a healthcare facility exempted pursuant to section 22.7 of this part that is not directly related to the provision of clinical health services or patient care activities, including but not limited to parking lots, information systems, and telephone systems.

What we'd like to do is encourage the Department to put together some sort of review process for nonclinical capital expenditures beyond application of just the definition. We are requesting this because in the past it's been our understanding that the Department has limited approval of noncapital expenditures only to parking lots, information systems, and telephone systems, even though the definition in the statute is more broad than broader than that to include capital expenditures that are not directly related to the provision of healthcare services and the language in the statute gives that list but says "including but not limited to."

We think that the statute and the general assembly is giving the Department the discretion to expand that list, to make judgment about what is not related to, what expenditures are not related to clinical services. So for example, roof repair, landscaping, maybe window replacement, HVAC systems, things like that. We would like to see some sort of process to that effect or a policy that would allow facilities to come forward and do that kind of work without having to go through a CON. There's a significant, you know, aging issue with buildings in the State of Rhode Island. We

see this with particular, particularly with facilities like nursing homes and our concern is that by limiting nonclinical expenditures only to parking lots, information systems, and telephone systems that discourages certain facilities from coming forward with plans and doing something particularly when there's a big improvement that needs to be done. And we're also going to supplement this testimony with a written testimony as well. Thank you.

Hearing Officer Roberts: Thank you. The next speaker is Denise Panichas.

Ms. Panichas: Good morning, my name is Denise Panichas, D-E-N-I-S-E, P-A-N-I-C-H-A-S, I am here as the executive director of the Samaritans of Rhode Island to talk about the proposed amendment removing drug and alcohol abuse treatment centers from definition of health care facility. As the director of the Samaritans for the last seventeen years and a former member of the Health Services Council I'm happy to be able to do this. For us, self-management, self-care management issues are considered key to controlling healthcare costs, but as we all know it's almost impossible to do.

In giving the starting point for licensing healthcare facilities is in the statute 23-17-3 which says "Promote appropriate access and safe and adequate treatment for individuals receiving healthcare facility services" and the key is safe and adequate treatment. So the illustrative questions that I would like to bring forth is what is health oversight as it relates to drug treatment programs to ensure better outcomes that are consistent with all state health plans and their goals. Right now it is, to the best of my knowledge, only the professional license, meaning the doctor, the nurse, the social worker, that they have control over. And yet substance abuse treatment programs are providing healthcare, so especially as no one person comes to any facility such as that with just one health problem.

On our crisis hotline individuals and families are frustrated among many issues with the inability to understand minimum standards of healthcare and how to coordinate that care, especially those who are presenting comorbid issues. There is an unmet need to help the public navigate through clearly defined, consistent definitions, standards, and licensure so service providers, both facilities and licensed professionals, are held accountable and the public can effectively navigate and advocate for their own care.

With patients receiving healthcare from myriad agencies and facilities not licensed in a standardized way or through a single portal, how do treating physicians know what these various agencies and facilities are actually doing to their patients that can impact on their overall health of their patients, how do they effectively treat? Like health, does BHDDH use a continuity of care form for agencies and facilities treating licensed professionals providing care under their jurisdiction? To the best of my knowledge I didn't see any on their website, it may be there but again this is not about market share, this is about oversight and making sure that the public has a safe place where they can go and hold people accountable for the coordination of their care.

The point of creating a super agency like BHDDH was to help facilitate coordination between departments, and I'm hoping that this hearing provides an opportunity to look at the issue of defining the unmet need of healthcare standards in continuity of care. Thank you.

Hearing Officer Roberts: Thank you. The next speaker is Greg Mercurio, Jr.

Mr. Mercurio: Thank you, my name is Greg Mercurio, Jr., M-E-R-C-U-R-I-O. I'm here as a consultant for Business Development Consultant Tollgate Radiology and I'm here at my capacity as an owner and board member of Bay Area Mobile Medical, as a founder and board member of Rhode Island PET CT, and a co-owner of Northern Rhode Island Radiology.

Thank you for providing me the opportunity to provide some thoughts and suggestions as to how the DOH may lessen the workload of the DOH staff as well as that of the Health Service Council, make our regulatory process less costly and burdensome for applicants, and more user friendly to the state's healthcare providers so as to encourage competition among providers that will lower costs increase quality of the healthcare system.

My suggestions and comments are simply meant to be constructive and thought provoking. I suggest that these just be considered as thoughts by the Department of Health and the staff.

First, that certificate of need should remain in the name of the entity that it was awarded to if the equipment that is subject to the CON is sold to a third party.

Second, CON should follow the applicant owner to which the CON was awarded and not travel with the technology as acquired as a result of the CON having been awarded.

A CON that is awarded must show meaningful progress in establishing the service that is subject to the CON within twelve months of the CON having been awarded, and must be operational within eighteen months of CON having been awarded, or the DOH must hold a public

show-cause hearing as to why the CON should not be rescinded or withdrawn. If a CON that is awarded and not implemented as above described, then with DOH approval the holder of the CON may transfer that CON through an administrative process to another qualified party.

If the entity that's awarded a CON is unable to implement the CON for any reason, and obtain a clinical license to operate, then under current regulations a process such as Change in Effective Control application is not available for a successor entity to step into the shoes of the entity holding the CON and who was unable to perform.

Since need has been established, a situation of unmet need now has been created so a process should exist whereby a qualified entity should be able to step into the shoes of the holder of the CON without having to incur the financial expense and time delay in order to become the successor holder of the CON by having to proceed through a full CON process. An administrative process should be constructed that simply vets the ability of the successor applicant in order to provide for the CON to be transferred.

In one-to-one upgrades there needs to be a better definition of new technology versus progressive technology. Under a strict interpretation of new technology under the current one-for-one upgrade criteria, the replacement technology is not supposed to permit the applicant to provide any new clinical services or any treatments with the new technology that could not be performed with the predicate technology. Essentially that means that a one-to-one upgrade should not be permitted for a CAT scanner from an eight slice CT to a sixty-four slice CT under current regs as there are additional tests that can be performed with the sixty-four slice CT versus an eight slice CT. Certainly that was not intended and that's not how the regulations have been promulgated but I believe that that language change should be made.

Also, such an upgrade is not new technology but rather progressive technology. We had situations in the past with PET CT CONs with a discussion of progressive versus new technology has been discussed. Same is true for a linear accelerator. Ten years ago, a linear accelerator to deliver radiation therapy did not involve stereotactic radio surgery, that was a separate unit known as a cyber knife. Over the last six years, all new linear accelerators have the capacity for providing stereotactic radio surgery, therefore a one-to-one upgrade of a general purpose linear accelerator to one that provides stereotactic radio surgery is not new technology and is in essence progressive technology.

Last, as you are all aware I'm an advocate of the CON system and the high quality of work provided by Mike Dexter and his team as well as the Health Service Council. I'd just like to bring to your attention in the last eighteen months the Department of Justice and the FTC have authored joint statements and letters to Alaska and South Carolina raising concern that their CON processes as written and adjudicated may rise to the level of being anti-competitive and therefore in violation of federal law. I suggest that these letters be reviewed as part of the process that is underway. Of specific concern is when CON regulations are amended to add additional services when it's clear they are only being enacted and added as barriers to competition for a new applicant.

Thank you for your time and attention, I'll be providing written comments and suggested language by September 17th.

Hearing Officer Roberts: Thank you. Are there any other persons present who would like to make a statement concerning the proposed regulations?

(PAUSE)

Hearing Officer Roberts: Thank you all for your attendance and for your patience and for the information you've offered, and this hearing is now closed.

(Hearing closed at 11:00AM)