IN THE COURT OF APPEALS OF TENNESSEE
AT NASHVILLE
October 13, 2015 Session

COVENANT HEALTH v. TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY, ET AL.

Appeal from the Chancery Court for Davidson County
No. 14128III Ellen H. Lyle, Chancellor

No. M2014-02538-COA-R3-CV – Filed April 14, 2016

This appeal arises out of the Tennessee Health Services and Development Agency's decision to grant a certificate of need to a company to acquire and operate a linear accelerator; the decision was opposed by another company that operated a linear accelerator. After a contested case hearing, an administrative law judge issued an initial order holding that the certificate of need should not have been granted. On the applicant's appeal, the agency reviewed the initial order and reversed it. The company which contested the application filed a petition for review in chancery court, where the Chancellor reversed the agency's decision, finding that it was not based on substantial and material evidence. On appeal to this court, we conclude that substantial and material evidence existed to support the agency's decision to issue the certificate of need. We therefore reverse the order of the chancery court and remand the case for entry of an order affirming the agency's decision.

Tenn. R. App. P. 3 Appeal as of Right; Judgment of the Chancery Court Reversed and Case Remanded

RICHARD H. DINKINS, J., delivered the opinion of the court, in which FRANK G. CLEMENT, JR., P.J., M.S., and J. STEVEN STAFFORD, P.J., W.S., joined.

Herbert H. Slatery, III, Attorney General and Reporter, Andree S. Blumstein, Solicitor General, and Sue A. Sheldon, Senior Counsel, for the appellant, Tennessee Health Services and Development Agency.

W. Brantley Phillips, Jr., Jeffrey P. Yarbro, and Matthew J. Sinback, Nashville, Tennessee, for the appellant, East Tennessee Radiation Therapy Services, LLC.

G. Bryan Jackson, Travis B. Swearingen, Nashville, Tennessee, for the appellee, Covenant Health.

OPINION

I. FACTUAL AND PROCEDURAL HISTORY

This is an appeal of an order of the chancery court reversing the Tennessee Health Services and Development Agency's issuance of a Certificate of Need for a linear accelerator, a device used in the treatment of cancer.

Tenn. Code Ann. § 68-11-1607 requires that healthcare facilities or entities desiring to acquire major medical equipment or initiate certain healthcare services apply for and receive a Certificate of Need ("CON") from the Health Services and Development Agency ("HSDA").[1] Review of CON applications is governed by Tenn. Code Ann. § 68-11-1608 and -1609, as well as Tenn. Comp. R. & Regs. Rule No. 0720-11-.01. For a CON to be granted, HSDA must determine that "the action proposed in the application is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities or services." Tenn. Code Ann. § 68-11-1609(b).

In August 2011, East Tennessee Radiation Therapy Services ("ETRTS") applied for a CON to acquire a linear accelerator, initiate outpatient radiation therapy services, and establish an ambulatory surgical treatment center limited to radiation therapy services at its Dowell Springs medical campus in Knoxville, Tennessee.[2] Covenant Health

[1] The HSDA "has jurisdiction and powers relating to the certification of need and related reporting of all health care institutions," and is composed of eleven members, including: the comptroller of the treasury; the state director of TennCare or its successor; the commissioner of Commerce and Insurance; three consumer members; an executive officer of a hospital or hospital system; a representative of the nursing home industry; a licensed physician; a representative of the home care industry; and a representative of the ambulatory surgical treatment center industry. Tenn. Code Ann. § 68-11-1604. References to "members" or "agency members" herein are to these persons.

[2] A linear accelerator (or "LINAC") is a piece of equipment used in the treatment of cancer and delivers a beam of high energy photons to the location of the patient's tumor; the LINAC can be used in combination with proton beam therapy, which uses a controlled beam of protons to precisely localize radiation dosages to tumors. ETRTS was granted a CON for proton beam therapy services in 2010. The CON application at issue in this case stated that "Radiation therapy with a linear accelerator '(linac)' is needed by many patients who will use this [Dowell Springs] campus often simultaneously with the chemotherapy and proton therapy they will receive here."

("Covenant"), a company that owns several linear accelerators in the region, opposed ETRTS's CON application by sending a letter to HSDA's executive director, Melanie Hill. Representatives of Covenant appeared to express opposition at HSDA's meeting on December 14, 2011, at which ETRTS's CON application was considered. The HSDA members voted to approve the application. HSDA's executive director sent a letter to John Wellborn, the consultant hired to submit ETRTS's CON application, which stated that the "Agency found the application to meet the three (3) statutory criteria in accordance with T.C.A. § 68-11-1609(3)(b)[sic][, and that t]his decision was reached following consideration of the written report of the Department of Health/Office of Health Policy, the State Health Plan, the general criteria established by [HSDA] Rules, and all evidence presented on the application."[3] Covenant subsequently petitioned HSDA for a hearing, and the agency initiated a contested case proceeding as provided in Tenn. Code Ann. § 68-11-1610.

An administrative law judge ("ALJ") held a hearing over eight days in January 2013 at which Covenant presented five witnesses and ETRTS presented seven.[4] On May 30, 2013, the ALJ entered an Initial Order concluding that "Covenant had carried its burden of proof by a preponderance of the evidence that the CON granted to ETRTS fails to meet the statutory and regulatory criteria for such action, specifically the requirement that there be a demonstrated need for the project." ETRTS appealed the initial order to the agency, pursuant to Tenn. Code Ann. § 68-11-1610(e)[5] and at the agency's regular

[3] After the CON was issued, ETRTS procured a linear accelerator and began treating patients with it in August 2012.

[4] Covenant's witnesses were: Gordon Lintz, past president and former chief administrative officer of Thompson Cancer Survival Centers and Thompson Oncology Group and, at the time of trial, president of Morristown Hamblen Hospital, all of which were owned by Covenant; Deborah Kolb Collier, Ph.D., healthcare management consultant; Chester Ramsey, Ph.D., chief medical physicist for Thompson Cancer Survival Centers; Joseph Dawson, retired administrator and consultant to the CEO and board of Blount Memorial Hospital; and Anthony L. Spezia, president and CEO of Covenant.

ETRTS's witnesses were David Millhorn, Ph.D., executive vice president for the University of Tennessee System; Terry Douglass, Ph.D., founder of Provision Trust, which owns ETRTS; Dr. Carl J. Rossi Jr., physician who is board certified in radiation oncology and serves as medical director of the Scripps Proton Therapy Center in San Diego; Dr. Russell F. DeVore III, board-certified in internal medicine and medical oncology and practices at Tennessee Cancer Specialists in the Dowell Springs campus; Dr. Alan G. Meek, board-certified in internal medicine and radiation oncology and the medical director at ETRTS; Daniel J. Sullivan, healthcare management consultant; and David C. Wood, a Certified Public Accountant who testified as an expert in the areas of business accounting and financial analysis.

[5] Tenn. Code Ann. § 68-11-1610(e) reads as follows:

> Initial orders of the administrative law judge in contested cases may be appealed in

meeting on July 24, the members voted 7 to 1 to grant the petition for review of the initial order, limited to examining the question of whether there was a need for the linear accelerator as required by Tenn. Code Ann. § 68-11-1609(b). After the meeting, Covenant and ETRTS submitted written arguments and the agency members were each supplied with a copy of the record developed before the ALJ. *See* Tenn. Comp. R. & Regs. 0720-13-.03.

At the agency's regular meeting on November 20, 2013, counsel for ETRTS and Covenant presented oral arguments; the members asked questions and made comments, at the conclusion of which they voted 5 to 3 to overturn the initial order. A final order was entered on January 13, 2014, granting the CON to ETRTS.

Covenant filed a petition for review of HSDA's final order in the Davidson County Chancery Court on January 30, 2014. The petition alleged the following bases for reversal: that the final order "violated constitutional and/or statutory provisions," Tenn. Code Ann. § 4-5-322(h)(1); that the final order "was generated by a procedure which was in excess of or in violation of HSDA's statutory authority and/or was otherwise improper and should be reversed," Tenn. Code Ann. § 4-5-322(h)(2) and (3); that "the way in which the Initial Order in this case was discarded by a narrow majority of the HSDA, after only a few minutes of non-substantive discussion and without any meaningful review of a year-long contested case process, was arbitrary and capricious and completely undermined the purpose of the contested case process," Tenn. Code Ann. § 4-5-322(h)(4); and that the final order "was unsupported by evidence that was both substantial and material in light of the entire record," Tenn. Code Ann. § 4-5-322(h)(5)(A).

After briefing and oral argument, the Chancellor entered a memorandum opinion and order concluding that HSDA's decision was not supported by substantial and material evidence. Pursuant to this order, the Chancellor reversed HSDA's Final Order and denied the CON to ETRTS.

ETRTS and HSDA appeal pursuant to Tenn. Code Ann. § 4-5-322. ETRTS articulates the following issue:

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writing to the agency. The agency may decline to hear any appeal. If the agency reviews the order, it must do so in accordance with the Uniform Administrative Procedures Act. If the agency declines to review the order, the requesting party may appeal the order to the Davidson County chancery court in accordance with the Uniform Administrative Procedures Act.

> Whether the Chancery Court misapplied the standard of review and substituted its judgment for that of the Heath Services and Development Agency when the Chancery Court concluded that the HSDA's decision to issue a certificate of need to Appellant East Tennessee Radiation Therapy Services LLC was not supported by substantial and material evidence.

HSDA phrases the issue as follows:

> In review of the administrative decision of the Tennessee Health Services and Development Agency to award a certificate of need for the establishment of a linear accelerator to provide radiation therapy, did the chancery court err by reweighing evidence and concluding that the decision was unsupported by substantial and material evidence in the record?

II. STANDARD OF REVIEW

Our review of HSDA's decision is governed by the standard set forth at Tenn. Code Ann. § 4-5-322(h):

> The court may affirm the decision of the agency or remand the case for further proceedings. The court may reverse or modify the decision if the rights of the petitioner have been prejudiced because the administrative findings, inferences, conclusions or decisions are:
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> (1) In violation of constitutional or statutory provisions;
> (2) In excess of the statutory authority of the agency;
> (3) Made upon unlawful procedure;
> (4) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion; or
> (5)(A) Unsupported by evidence that is both substantial and material in the light of the entire record.
> (B) In determining the substantiality of evidence, the court shall take into account whatever in the record fairly detracts from its weight, but the court shall not substitute its judgment for that of the agency as to the weight of the evidence on questions of fact.

Tenn. Code Ann. § 4-5-322. The limits of such review were explained in *Wayne County v. Tennessee Solid Waste Disposal Control Bd.*:

> Courts defer to the decisions of administrative agencies when they are acting within their area of specialized knowledge, experience, and

> expertise. Accordingly, judicial review of an agency's action follows the narrow, statutorily defined standard contained in Tenn. Code Ann. 4-5-322(h) rather than the broad standard of review used in other civil appeals. The narrower scope of review used to review an agency's factual determinations suggests that, unlike other civil appeals, the courts should be less confident that their judgment is preferable to that of the agency.

756 S.W.2d 274, 279 (Tenn. Ct. App. 1988) (internal citations omitted). "Courts do not review the fact issues *de novo* and, therefore, do not substitute their judgement [sic] for that of the agency as to the weight of the evidence, even when the evidence could support a different result." *Id.* (internal citation omitted) (citing *Humana of Tennessee v. Tennessee Health Facilities Comm'n,* 551 S.W.2d 664, 667 (Tenn. 1977); *Grubb v. Tennessee Civil Serv. Comm'n,* 731 S.W.2d 919, 922 (Tenn. Ct. App. 1987); *Hughes v. Board of Comm'rs,* 319 S.W.2d 481, 484 (1958)).[6]

III. ANALYSIS

HSDA determined that compelling reasons existed to depart from a strict application of the criteria in the state health plan,[7] specifically, that the proposed linear

[6] Covenant argues that we should engage in "rigorous analysis" and "subject the HSDA's reversal of [the ALJ's] Initial Order to intense scrutiny with a thorough *de novo* review of the evidentiary record." As noted earlier, our review is directed by Tenn. Code Ann. § 4-5-322(h); inherent in this statute is the expectation that our review will be thorough. *Wayne County*, 756 S.W.2d at 278, 280 (calling for a "searching and careful" review). To the extent Covenant asks that we exceed the parameters of § 4-5-322(h)(5) and reweigh the evidence, such review would be inconsistent with the standard we are compelled to apply, and we therefore decline to do so.

[7] Tenn. Code Ann. § 68-11-1609(b) reads in pertinent part:

> No certificate of need shall be granted unless the action proposed in the application is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities or services. In making such determinations, the agency shall use as guidelines the goals, objectives, criteria and standards in the state health plan. Until the state health plan is approved and adopted, the agency shall use as guidelines the current criteria and standards adopted by the state health planning and advisory board, and any changes implemented by the planning division pursuant to § 68-11-1625.

The state health plan referenced in this statute was created in 2009 by the Office of Health Planning and directs that the criteria in "Guidelines for Growth" — a document created in 2000 by the Health Planning Commission — as those guidelines which the HSDA should apply when examining a CON application. The Guidelines for Growth set forth the criteria for megavoltage radiation equipment like the linear accelerator at issue in this case. A 2011 Update to the State Health Plan instituted new CON criteria for

accelerator was needed to provide fully integrated combination therapy to maximize patient safety and treatment outcomes, to provide timely treatment for patients during proton center downtime, and as part of educational, research, and development initiatives. ETRTS and HSDA contend that the record contains substantial and material evidence in support of this determination; Covenant disagrees.

A. HSDA's Final Order

Our consideration of HSDA's decision entails a three-step review set forth in *McEwen v. Tennessee Department of Safety*:

> Tenn. Code Ann. § 4-5-322 requires courts to engage in a three-step analysis when they review a final administrative order. The court must first determine whether the agency has identified the appropriate legal principles applicable to the case. Then, the court must examine the agency's factual findings to determine whether they are supported by substantial and material evidence. Finally, the reviewing court must examine how the agency applied the law to the facts. This step is, of course, a highly judgmental process involving mixed questions of law and fact, and great deference must be accorded to the agency. At this stage, the court must determine whether a reasoning mind could reasonably have reached the conclusion reached by the agency, consistent with a proper application of the controlling legal principles.

173 S.W.3d 815, 820 (Tenn. Ct. App. 2005) (footnotes omitted) (citing *State of Maryland Comm'n on Human Relations v. Kaydon Ring & Seal, Inc.*, 818 A.2d 259, 275 (Md. Ct. Spec. App. 2003)).

No party asserts that the agency did not identify and apply the appropriate legal principles, and upon our review, we agree that Tenn. Code Ann. §68-11-1609(b) and Tenn. Comp. R. & Regs. Rule No. 0720-11-.01[8] are the appropriate standards.

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this type of equipment, effective December 31, 2011, but because the CON application at issue in this case was filed in August 2011, those criteria do not apply.

As recited in both the ALJ's initial order and the agency's final order and as is evident from our review of the agency proceeding, "all parties agree that an additional LINAC is not supported by the objective criteria set forth in the State Health Plan." However, the CON was granted upon the agency's conclusion that "the unique opportunities in healthcare, education, research and development that will be provided by the unique combination of resources at Dowell Springs, provide a compelling reason to depart from a strict application of the criteria for approval of a CON as set forth by the Guidelines."

[8] Tenn. Comp. R. & Regs. 0720-11-.01, "General Criteria for Certificate of Need," reads in pertinent part:

The Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:

(1) Need. The health care needed in the area to be served may be evaluated upon the following factors:

(a) The relationship of the proposal to any existing applicable plans;
(b) The population served by the proposal;
(c) The existing or certified services or institutions in the area;
(d) The reasonableness of the service area;
(e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, Tenncare participants, and low-income groups;
(f) Comparison of utilization/occupancy trends and services offered by other area providers;
(g) The extent to which Medicare, Medicaid, Tenncare, medically indigent, charity care patients and low income patients will be served by the project. In determining whether this criteria is met, the Agency shall consider how the applicant has assessed that providers of services which will operate in conjunction with the project will also meet these needs.

(2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:

(a) Whether adequate funds are available to the applicant to complete the project;
(b) The reasonableness of the proposed project costs;
(c) Anticipated revenue from the proposed project and the impact on existing patient charges;
(d) Participation in state/federal revenue programs;
(e) Alternatives considered; and
(f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.

(3) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:

(a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, the applicant's proposed Tenncare participation, affiliation of the project with health professional schools);
(b) The positive or negative effects attributed to duplication or competition;
(c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;
(d) The quality of the proposed project in relation to applicable governmental or professional standards.

We next examine the agency's factual findings to determine whether they are supported by substantial and material evidence. The agency made 54 factual findings, which span 22 pages of the final order.[9] While the appellants have cited testimony which they contend is substantial and material evidence in support of the agency's decision, they have not clearly identified, with citation to the record, the specific factual findings they contend are supported by this evidence.[10] Upon our review, we have determined that the following findings are most pertinent to the issues presented in this appeal and will conduct our analysis accordingly:[11]

> 30. While it is not absolutely necessary for the proton beam center and a linear accelerator to be located on the same campus or owned and operated by the same entity, a preponderance of the testimony and statements in the record by experts with experience at proton therapy facilities is consistently to the effect that such complete integration is "certainly preferable," presents the "best scenario," "is in the best interests of the patients" and "in the best interests of patient care." According to these experts, such an arrangement provides the best option "for ensuring the lowest possible risk to the patient" and avoids an "increased risk in using separate planning teams and planning systems for the two types of therapies" that "is not in the best interest of the patient." Such integration is universally considered, in a word, "optimal."
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> 31. Both the proton beam center and the ETRTS facility are organized for "open model" staffing, which allows for any properly qualified physician to utilize the equipment regardless of the physician's affiliation with another

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> (5) Certificate of need conditions. In accordance with T.C.A. § 68-11-1609, The Agency, in its discretion, may place such conditions upon a certificate of need it deems appropriate and enforceable to meet the applicable criteria as defined in statute and in these rules.

[9] Factual findings 1–4 detail the parties to the case; factual findings 5–11 detail the procedural history of the case; factual findings 12–15 contain the criteria to be applied by the agency in examining a CON application; factual findings 16–21 recount the testimony of both parties' health planning experts as to the criteria of need; factual findings 22–42 detail the various reasons ETRTS contended that a linear accelerator was needed and testimony of Covenant's witnesses to the contrary; factual findings 43–52 pertain to the criteria of economic feasibility and the orderly development of healthcare. The Agency attached as an exhibit to its final order a copy of the ALJ's initial order with modifications and additions identified therein; this was very helpful to our review.

[10] *See* Tenn. R. App. P. 27(a)(7).

[11] Citations in the order to the record omitted.

provider. Covenant has committed to having its physicians fully trained and qualified in order that they will be able to treat patients at the proton beam facility.

32. Chester R. Ramsey, Ph.D., is the Chief Medical Physicist for the Thompson Centers, which are owned by Covenant. As previously stated, Thompson operates 10 locations in the service area. Dr. Ramsey is an adjunct professor at the University of Tennessee's (UT) School of Engineering and has taught medical physics courses at UT since 1997. For the past 15 years, Thompson has been training medical physics residents on the most advanced treatment techniques with its physics residency program offered through UT. Although Dr. Ramsey has written four papers on issues relating to proton therapy, he admitted in his testimony that most of what he knows about proton therapy is from what he has "heard or learned from something on the internet." He is not a medical doctor and does not have clinical responsibility for radiation therapy patients at Covenant. He has never worked at a proton facility and has no experience with trying to import or use a combination therapy treatment plan. Dr. Ramsey also admitted that he is not in regular communication with any proton facilities and has only visited a proton facility once in his career — in Switzerland in 2007.

33. Dr. Ramsey admitted in his testimony that he "has never laid hands on a patient who has received proton therapy." Dr. Ramsey nonetheless testified that he has extensively prepared for the opportunity to participate in the open and collaborative model proposed for the proton beam center and believes that, through careful planning and collaborative effort, sequential patients can be safely treated at an off-site linear accelerator operated by Thompson or one of the other local providers in the service area. However, Dr. Ramsey's plan to use the same type of immobilization devices and Covenant's own packages of the same type of planning and medical records systems as those used at the proton therapy center essentially amounts to an attempt at the very sort of "plug and play" coordination that Dr. Rossi has testified is not feasible based on his extensive, hands-on experience.

34. Another disadvantage to splitting therapy between two separate providers is that it almost always requires that the patient undergo additional diagnostic scanning for treatment planning purposes. Dr. Ramsey has acknowledged that patients arriving for treatment at Covenant from other radiation therapy facilities must be re-scanned. This additional scanning exposes the patient to additional radiation, requires the use of

anesthesia in many pediatric patients, delays treatment and increases the cost of treatment to the patient and/or provider. It is also uncertain whether these duplicate diagnostic scans would be covered by insurance.

35. Although Covenant is confident that it and other area providers could meet the demand for LINAC services generated by patients requiring combination proton therapy and traditional radiation therapy, there is debate as to exactly what percentage of proton beam patients would need combination therapy. Based on his experience at Lorna Linda, Dr. Rossi testified that 10-20% of patients will need combination therapy. Information presented from other facilities suggests that the percentage varies -- ranging from five percent (5%) at the Indiana Health Proton Therapy Center and the two ProCure proton therapy facilities and ten to twenty percent (10-20%) at Hampton University. Provision has estimated that it will treat 670 patients annually at the proton beam center by the second year of operation. If one assumes that 5-10% of patients needing combination therapy is a more reasonable estimate than Dr. Rossi's 10-20% estimate, one can assume that less than 65 patients per year treated at the ETRTS proton beam center would require combination therapy. In terms of numbers alone, it is possible that Covenant's Thompson Centers, as well as the other providers in the service area, would be able to absorb this relatively small number of new patients at their LINAC centers. However, that fact does not address the concerns about safety and practical feasibility of splitting combination treatment between providers.

36. The ETRTS LINAC is also expected to be used to provide treatment to proton therapy patients during times when the proton equipment is out of service for unscheduled maintenance or repairs. Because proton therapy equipment is complex, proton therapy facilities occasionally experience unexpected shutdowns for unscheduled maintenance and repairs, which have been known to last for weeks and even months. Having interruptions of that length — or even interruptions of just a few days — in the course of proton beam therapy would adversely affect the outcome of treatment for the patients affected. Dr. Rossi testified that, in his experience, suddenly sending all proton patients to existing area providers for treatment in the event of a proton facility shutdown is not a practical solution. Even assuming another provider, with its own patient obligations, could absorb any number of displaced proton patients into its schedule, there would inevitably be a delay in treatment for the length of time required to re-scan the patient and create a treatment plan at the new facility. Dr. Rossi testified that in his experience at Loma Linda, when the proton equipment

experienced a shutdown they were able to treat the proton patients on their already heavily-utilized LINAC by running extended shifts and providing treatments on weekends as needed. He testified that this transition was facilitated by having already developed treatment plans for those patients for treatment on a LINAC "under the umbrella of an integrated network where we didn't have to take, for example, three days, four days a week to plan a patient to go on x-rays." For the reasons addressed above, the delay and the re-scanning associated with moving a patient to another provider can have adverse consequences in terms of treatment outcome and cost.

37. It is undisputed that the proton beam center is expected to open and to treat patients successfully regardless of the outcome of this CON proceeding, and that it is possible to operate a proton therapy facility without having access to an integrated linear accelerator. The lack of such access, however, will negatively impact the proton center's ability to deliver combination therapy, as well as its ability to get its patients treated in a timely manner in the event of proton equipment downtime.

38. Another reason offered by ETRTS in support of the need for a LINAC at Dowell Springs was the continuum of care and convenience it would provide patients receiving treatment from the two physician groups located there. Knoxville Comprehensive Breast Center (KCBC) and Tennessee Cancer Specialists (TCS) re-located their offices to Dowell Springs in 2008 and 2009 respectively. It must be noted that at the time of the re-location of these two physician groups there was no LINAC at Dowell Springs. . . .

39. . . . Dr. DeVore testified that in 2011 and early 2012, the TCS physicians at Dowell Springs were experiencing increasing delays in getting their patients scheduled for radiation therapy with an existing provider, with some patients waiting as long as 2-3 weeks. ETRTS has enabled TCS to get patients scheduled for radiation therapy within the same day or week, and allows for convenient, in-person coordination between medical and radiation oncologists and their staffs.

40. As an additional factor in demonstrating the need for a LINAC at Dowell Springs, ETRTS emphasized the potential for research and educational opportunities that will exist at the medical complex. An important aspect of the Provision complex at Dowell Springs is the Center for Biomedical Research (CBR). Currently, clinical trials are being conducted on patients receiving cancer treatment from the providers at Dowell Springs. It is the goal of Dr. Douglass to significantly enhance the

research capabilities at Dowell Springs. He believes that having access to both a linear accelerator and a proton beam on site will increase clinical trial capabilities and lead to a greater level of research. Dr. Douglass stated that he hopes to use the traditional radiation center and the proton therapy center to help develop the "next generation proton therapy equipment." Specifically, proton therapy facilities that exist today rely on equipment that typically costs $75-100 million and weighs 200-300 tons. Terry Douglass has formed a new venture at Dowell Springs — ProNova Solutions — with the goal to develop proton therapy equipment that costs $25 million, weighs less than 25 tons and has even better capabilities than current equipment. UT supports the ProNova Solutions initiative and hopes to collaborate with Dr. Douglass on it.

41. Alan G. Meek, M.D., has been the medical director at ETRTS since August 2012. Prior to coming to ETRTS, Dr. Meek had been the chairman of the Radiation Oncology Department at the State University of New York at Stony Brook Health Sciences Center. Dr. Meek intends to conduct a variety of research using the ETRTS linear accelerator, including collaborating with the medical oncologists on clinical trials, continuing his own research on the best position in which to deliver radiation to breast cancer patients and experimenting with radiopharmaceuticals created in the on-site cyclotron to improve the diagnostic imaging used for cancer treatment planning. Dr. Meek also is collaborating with UT on the development of a radiation oncology department, which the UT School of Medicine currently lacks. Dr. Meek is in the process of receiving a faculty appointment with the UT Department of Biomedical Engineering as well as a clinical appointment with the School of Medicine.

42. Provision is also actively pursuing collaborative research efforts with the Oak Ridge National Laboratory (ORNL) and UT. David Millhorn, Ph.D., is the Executive Vice President and Vice President for Research and Economic Development for UT. According to Dr. Millhorn, one of the many projects UT is discussing with Provision and ORNL is the development of a new Joint Institute for Radiologic Sciences and Advanced Imaging which would use the Dowell Springs campus as an education, training and research site. UT currently does not have an accredited medical physics program, and it is in the process of establishing such a program. Dr. Millhorn testified that UT is discussing with Provision a collaborative partnership on this project.

In our analysis, we are mindful that "[w]hat amounts to substantial evidence is not precisely defined by the statute. In general terms, it requires something less than a preponderance of the evidence, but more than a scintilla or glimmer." *Wayne Cty.*, 756 S.W.2d at 280 (internal citations omitted) *(*citing *Consolo v. Federal Maritime Comm'n,* 383 U.S. 607, 620, (1966) *Pace v. Garbage Disposal Dist.,* 390 S.W.2d 461, 463 (Tenn. Ct. App. 1965)). "'Substantial and material evidence' consists of such relevant evidence as a reasonable mind might accept as adequate to support a rational conclusion. Substantial and material evidence furnishes a reasonably sound basis for the agency's decision." *McEwen*, 173 S.W.3d at 820 n.8 (Tenn. Ct. App. 2005) (citing *Freedom Broadcasting of TN, Inc. v. Tenn. Dep't of Revenue,* 83 S.W.3d 776, 781 (Tenn. Ct. App. 2002); *Martin v. Sizemore*, 78 S.W.3d 249, 276 (Tenn. Ct. App. 2001)). If such evidence exists in the record, "an agency's factual determination should be upheld." *Wayne Cty.*, 756 S.W.2d at 279-80 (citing *Southern Ry. v. State Bd. of Equalization,* 682 S.W.2d 196, 199 (Tenn. 1984); *Sweet v. State Technical Inst.*, 617 S.W.2d 158, 161 (Tenn. Ct. App. 1981)). Even in cases involving scientific or technical evidence, the "substantial and material evidence standard" in Tenn. Code Ann. § 4-5-322(h)(5) requires a searching and careful inquiry that subjects the agency's decision to close scrutiny. *Wayne Cty.*, 756 S.W.2d at 280 (citing *Crounse Corp. v. ICC,* 781 F.2d 1176, 1187 (6th Cir.), *cert. denied,* 479 U.S. 890 (1986); *Cranston v. Clark,* 767 F.2d 1319, 1321 (9th Cir.1985)).

We have reviewed the evidence cited by the parties in their briefs and have conducted our own thorough and independent review of the testimony and exhibits introduced at the hearing. Based on the entire record, and taking into our consideration the conflicting evidence, we conclude that the record contains substantial and material evidence which supports HSDA's factual findings. While Covenant asserts that "a battle of the experts" existed in this case and devotes several pages of its brief to highlight the conflicting testimony of its witness, Dr. Ramsey, and that of Dr. Rossi,[12] "when conflicts in expert testimony arise, it is the agency's prerogative to resolve them, not the court's." *Wayne Cty.* 756 S.W.2d at 281 (citing *Webb v. Gorsuch,* 699 F.2d 157, 160 (4th Cir.1983)). The agency resolved the conflict in favor of ETRTS, as was its prerogative. We proceed to discuss the evidence supporting the findings.

Dr. Rossi's testimony provides substantial and material evidence in support of HSDA's Finding 30 that fully integrated combination therapy is "optimal."[13]

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[12] Without citation to the record, Covenant also contends that the ALJ "found Covenant's expert, Dr. Ramsey, to be far more credible" and made an adverse credibility determination regarding Dr. Rossi. Our review of the initial order reveals no such credibility determinations by the ALJ. Regardless, *McEwen* instructs that an agency is permitted to substitute its judgment for that of the ALJ on all matters, including the credibility of witnesses. *See McEwen*, 173 S.W.3d at 823.

[13] Dr. Rossi testified that that "the installation of [a] linear accelerator on the Provision campus as part of

As to Finding 31, the testimony of Drs. Douglass, Rossi, and Ramsey provides substantial and material support for the finding that ETRTS has an open staffing model and that Covenant has committed to training its physicians on proton therapy.[14]

To the extent that the excerpts of the testimony of Drs. Ramsey and Rossi are recounted in Findings 32-34, the testimony is correctly reproduced in the agency's findings and is substantial and material evidence in support of those findings.[15]

Additionally, with respect to Finding 34, the testimony of Dr. Rossi provides substantial and material evidence for these findings that splitting combination therapy between different providers requires the patient to undergo additional diagnostic scanning for treatment planning purposes.[16]

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their proton facility is clinically necessary for the care of patients receiving both proton therapy alone and those receiving therapy with a combination of protons and x-rays"; that combination therapy "is best delivered and should be delivered in a totally integrated facility where you have the same treatment team performing both modalities, the same physician, physicist, dosimetrist, technologist, integrated treatment planning package, so that everybody is, in effect, playing from the same playbook"; and that to be integrated, the treatment system must have "an integrated team of physicians, physicists, dosimetrists, therapists . . . not just . . . having software that talks to each other."

[14] Dr. Douglass testified that "we want to be open to the community, any patient, any physician, and any hospital system to have access to what we do in our -- with our radiation therapy center, imaging center, our proton therapy center, with our wellness, physical therapy."

Dr. Rossi testified that he knew ETRTS was an "open model," and that, to him, the phrase meant "that an appropriately credentialed physician can treat a patient with both modalities . . . [i.e.,] "[t]hey could treat with the proton machine and they could treat with the linear accelerator located at the proton center."

Dr. Ramsey testified that "[t]he proton center was approved under an open model by the HSDA so that a credentialed -- any credentialed radiation oncologist can use that facility"; that "though we've got a different [treatment planning system], it's [his] understanding that Covenant will purchase the same planning system used at the proton facility" as well as the same immobilization devices and a license from the electronic medical record system vendor, if required to connect to ETRTS's system; and that his staff would be trained on proton therapy.

[15] Dr. Rossi testified that "These things are not plug and play. You're talking about very complex treatment planning packages that often do not play very well with each other at all. And it's not just the technical part; it's the human part. You can have all of the nice -- you can have an identical piece of software, but if you don't have people who are using this on a daily basis and are used to doing things in a certain way, you're just opening yourself up literally for disaster"; that "It is an extremely difficult thing to do, to try to integrate the technology" [due to, for example] "information technology, data transfer issues that are -- they seem very innocuous at the outset but they become formidable."

[16] Dr. Rossi testified that "in most cases [of trying to coordinate linear accelerator treatment with an outside facility] in my experience, they then would have to replan the patient, repeat a CT scan, repeat

As to Finding 35, that a small percentage of patients will require combination therapy and that "safety and practical feasibility" concerns exist when combination therapy is split between different providers, the testimony of Drs. Ramsey, Rossi, and Meek, as well as that of Mr. Dawson support this finding.[17]

As to Finding 36, regarding the need for a linear accelerator to serve as a treatment option during proton center downtime, the testimony of Dr. Rossi substantially and materially supports the HSDA's findings.[18]

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computer planning, a several-day delay to get that person started"; that "[t]here would be treatment delays"; that "if you can avoid having to do a rescan, which in my experience virtually always occurred when a patient went to an outside facility, it's to that person's benefit. There's also – more mundane but also important, many insurers will not pay for that. The patient gets stuck with the cost."

[17] Dr. Ramsey, chief medical physicist for Covenant's Thompson Cancer Survival Center, testified that "for a certain subset of patients, the -- so say for 10 percent of patients that would be treated at a typical proton therapy facility, there's a small number that requires linear accelerator treatments in addition to the proton therapy"; that "[i]t is complex to add together multiple treatment types"; that the risk of error increases with the complexity of treatment types; and that patient safety is the number one concern.

Dr. Rossi testified that despite the superiority of proton beam therapy to traditional x-ray therapy from a linear accelerator, "there are clinical situations where it's necessary" to treat a "large region which can contain microscopic disease," such as "in the case of head and neck cancer" and with advanced prostate cancer; that 10 to 20 percent of proton patients required combination treatment; that with regard to head and neck cancer patients, 75 percent of patients require combination therapy; and that insurers may not pay for re-scanning at the other facility.

Dr. Meek testified that combination therapy at ETRTS would be "a seamless operation with an overlapping staff structure. It will have a similar treatment setup and treatment planning system[,] couches for how the patients are placed for treatment and immobilized." He also testified about the importance of reproducible patient positioning and immobilization for each treatment and ETRTS's use of identical patient positioning equipment "because you want to have the patient in the same position for treatment as you did when you were setting them up for the treatment" because "[e]very time they come in, they have to be set up perfectly to be sure that treatment is given properly," citing negative consequences if the treatment field is off by even 2 or 3 millimeters.

Mr. Dawson agreed on cross examination that better care can be offered when cancer treatments are performed in one location.

[18] Dr. Rossi testified that with "emerging" and "maturing" technology like proton therapy, the machines can have significant issues or machine downtime, during which "the only effective way to [treat those proton patients] is to be able to . . . have an integrated LINAC where you can plan those patients and treat those patients expeditiously so they're not having a treatment break."

As to Finding 37, the testimony of Drs. Douglass, Ramsey, and Rossi provide substantial and material support for the HSDA's findings as to the successful operation of the proton beam without a linear accelerator.[19]

As to Findings 38 and 39, regarding the continuum of care and convenience for patients, the testimony of Mr. Sullivan and Dr. DeVore provide substantial and material support for the HSDA's findings.[20]

As to Findings 40, 41, and 42, regarding the development, educational, and research opportunities for the linear accelerator, we conclude that the testimony of Drs. Douglass, Meek, and Millhorn provide substantial and material evidence in support of the agency's findings.[21]

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[19] The experts agreed that proton therapy does not require a linear accelerator in order to operate, and that, for combination therapy, the linear accelerator and the proton beam equipment do not have to be in the same physical location. The testimony set forth in footnotes 10 and 11 provides substantial and material support for the remaining facts as found by HSDA in Finding 37.

[20] Mr. Sullivan testified that that a linear accelerator at Dowell Springs "is needed to serve the patients who are already coming to the campus . . . where there's an array of other types of cancer treatment and diagnostic services available [b]ut the one missing element is radiation therapy"; that it would make "sense from a planning perspective to allow these patients [who have chosen to come to the Dowell Springs campus for other cancer treatments] to have access to radiation therapy at the same location where their medical oncologists are located." Dr. DeVore testified that it is preferable to be able to deliver radiation therapy and chemotherapy at the same site for the reasons of "convenience, quality, coordination of care" and that he was able to get patients scheduled "in the same day, same week" on ETRTS's linear accelerator.

[21] Dr. Douglass testified that the linear accelerator at issue "will increase the clinical trial capability that we will have" at the Center for Biomedical Research located on the Dowell Springs campus; that "[t]here are clinical trials that need to go on to look at chemotherapy and conventional radiation therapy and proton therapy . . . being used concurrently"; that "from an academic point of view, . . . we can develop programs with the university, medical physics programs with the college of engineering[, and also] . . . have discussions and conversations going with UT Health Sciences Center in Memphis [which] do[es] not have a radiation oncology program"; that having both the proton beam and linear accelerator creates "the opportunity to do research . . . to train medical physicists and physicians in how to utilize this equipment"; and that he had previously had "several" discussions with the executive dean at the UT Health Sciences Center "with regard to how we're going to create a residency program at our campus."

Dr. Meek testified that he had "made contact with both the [University of Tennessee's] graduate school of medicine in Memphis about forming a radiation oncology department which they do not have now, and have also been approached by the University of Tennessee biomedical engineering department for faculty appointment"; that he wanted "to continue [his] research using the radiopharmaceuticals available at the Provision site", which would involve the linear accelerator because this research "will help define actually [sic] targets for treatment on the linear accelerator."

We are mindful that the ALJ and the Agency examined the same evidence and came to different conclusions.[22] This disagreement leads to "closer judicial scrutiny of [the agency's] findings of fact." *McEwen*, 173 S.W.3d at 823. We have examined both the ALJ's and HSDA's factual findings consistent with this standard and conclude that the evidence supporting HSDA's findings is substantial and material. "If the record contains evidence sufficient to support the conflicting findings of the agency and the . . . administrative judge, the agency's findings must be allowed to stand even though the court might have reached a different conclusion on its own." *Id.* at 824. Examining the ALJ's and the agency's differing findings in this light, we apply the language in *Martin v. Sizemore* that "[b]ased on the record before us, we cannot conclude that reasonable persons can draw only one conclusion from the evidence" and hold that the record contains substantial and material evidence to support the HSDA's factual findings. *Martin*, 78 S.W.3d 249, 277 (Tenn. Ct. App. 2001).

Having concluded that substantial and material evidence exists to support HSDA's factual determinations, we next examine how the agency applied the law to the facts. This process involves "mixed questions of law and fact, and great deference must be accorded to the agency . . . [as we] determine whether a reasoning mind could reasonably have reached the conclusion reached by the agency, consistent with a proper application of the controlling legal principles." *McEwen*, 173 S.W.3d at 820 (citing *State of Maryland Comm'n on Human Relations*, 818 A.2d at 275).

In the final order, the agency cited the applicable statutory and regulatory authority, discussed the criteria of economic feasibility and orderly development of healthcare, and then discussed the criteria of need, making the following Conclusions of Law:

> 10. The ALJ concluded that this case turns on whether there is a need for a new linear accelerator in the Knoxville service area. The ALJ concluded

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Dr. Millhorn testified that having a linear accelerator at Dowell Springs would give "the foundation for a strong research program and cancer radiobiology"; that the Dowell Springs campus would serve as "another training site, education site, research site for the proposed Joint Institute of Radiologic Science and Imaging"; that UT faculty and students would have "controlled access" on the Dowell Springs campus; and that UT was supportive of ETRTS's application because "the linear accelerator, combined with the proton therapy accelerator, gives the university and its faculty and scientists a unique opportunity."

[22] When the agency makes its own factual determinations, the final order must identify any differences between its findings of fact and conclusions of law and those in the initial order. Tenn. Code Ann. § 4-5-315(i). HSDA properly identified the differences in its final order from those of the ALJ by attaching as an exhibit to its final order, a copy of the ALJ's initial order with modifications and additions identified therein; this document very helpful to our review.

that such a need does not exist, based on his finding that this project does not meet the objective criteria set forth in the State Health Plan to justify the addition of a new LINAC in the market. The HSDA disagrees with this Conclusion.

11. The parties agree that this project does not meet the objective criteria set forth in the State Health Plan for the addition of a new LINAC in the market. However, the HSDA concludes that those criteria alone do not determine whether there is need for a project, and this Agency may depart from them when other compelling considerations warrant doing so. Otherwise, the Agency's prior approval of the LINAC for Covenant in Sevier County, which is not projected to reach or exceed the minimum number of treatments or patients provided for by the State Health Plan for the foreseeable future, would effectively block the addition of any new linear accelerators to the service area regardless of the unique merits of any particular project. Moreover, it appears likely that growth and aging of the service area population, in addition to increased demand for health care services fueled by a recovering economy and increased access to health insurance under government mandate, will either increase the current LINAC utilization rate in the area or at least sustain it at the current level, which the parties agree allows the service to be very profitable.

12. As discussed above, there is a need for a LINAC to be fully integrated with the proton beam therapy equipment at Dowell Springs in order to maximize the safety and treatment outcomes for those patients who require combination therapy, regardless of their number. It is also needed in order to allow for the timely treatment of proton-only patients on a LINAC in the event of proton equipment downtime.

13. There is also a need for a LINAC as part of the educational, research and development initiatives being planned for Dowell Springs in collaboration with the University of Tennessee and ORNL. As the only site in East Tennessee with a proton beam therapy center, Dowell Springs is the only campus in the region on which students could be trained to treat patients on both proton equipment and conventional linear accelerator equipment. This training will be an important component of UT's accredited medical physics program and the UT School of Medicine's radiation oncology department, both of which are in development in collaboration with ETRTS and its affiliates at Provision. It is also the only campus in the region at which research and clinical trials could be conducted on-site comparing the efficacy of proton beam therapy and

> conventional radiation therapy. These opportunities are uniquely available at Dowell Springs and, as stated above, are to be encouraged and may result in advancements in cancer treatment that could not be made anywhere else in the region.

The order then concluded:

> 14. Covenant has NOT carried its burden of proof by a preponderance of the evidence that there is no demonstrated need for the ETRTS project. ETRTS has given several credible and compelling considerations to look beyond the Guidelines for Growth in evaluating this project. Accordingly, it is hereby ORDERED that the decision of the HSDA to grant the CON to ETRTS be AFFIRMED and the CON be GRANTED.

The agency granted the CON, applying the proper legal principles to factual findings which we have determined are supported by substantial and material evidence. Inasmuch as HSDA, not the judiciary, bears the legal mandate to administer the CON process, we acknowledge that "[t]he court's role is simply to determine whether the law's requirements have been met and to defer to an agency's decision if there is a sound basis in the record to support it." *Miller v. Civil Serv. Comm'n of Metro. Gov't of Nashville & Davidson Cty.*, 271 S.W.3d 659, 669 (Tenn. Ct. App. 2008) (citing *Bobbitt v. Shell*, 115 S.W.3d 506, 512 (Tenn. Ct. App. 2003)). Because the record contains evidence that compelling reasons existed to look beyond the Guidelines for Growth in the state health plan, as detailed in the introductory paragraph to Section III, *supra*, the record shows that there is a factual and legal basis which supports HSDA's decision; we defer to the agency's decision and affirm the agency's final order. *Id. at* 665 (citing *Armstrong v. Metro. Nashville Hosp. Auth.*, No. M2004-01361-COA-R3-CV, 2006 WL 1547863, at *2 (Tenn. Ct. App. June 6, 2006).

B. Other Matters

At the trial court Covenant contended that: (1) HSDA applied the incorrect standard of review to the ALJ's initial order; (2) HSDA's decision was arbitrary and capricious because it did not consider the Guidelines for Growth during its deliberations; and (3) HSDA's decision was not supported by substantial and material evidence. The Chancellor ruled against Covenant's position with respect to (1) and (2) and for Covenant as to (3).

Covenant does not assign error or request relief from either of the Chancellor's holdings against it, though it does devote several pages of its brief on appeal to reiterating the arguments it raised in the trial court. While the failure to raise an issue on appeal

would normally be a waiver of the issue, we have discretion pursuant to Tenn. R. App. P. 13(b) to consider a matter not raised by the parties. In the interest of clarifying the appropriate standard of review to be applied by the HSDA when reviewing a decision of an ALJ and also to clarify the application of Tenn. Code Ann. § 68-11-1609(b) to the determination of whether the agency's action was arbitrary and capricious, we will consider the Chancellor's order as it relates to holdings (1) and (2).

(1) Standard of Review applied in HSDA's Review of an Initial Order

Covenant asserted before the trial court and in its brief on appeal that Tenn. Comp. R. & Regs. 0720-13-.03 required the HSDA's review to be "in the nature of appellate review," which Covenant construed as "a new standard of review" requiring HSDA to show "an even higher standard of deference . . . to the ALJ's order." Covenant contended that reversal was warranted because HSDA applied an improper *de novo* review to the contested case proceeding, which resulted in its substitution of findings of fact and reversal of the initial order.

The Chancellor examined Tenn. Code Ann. § 4-5-315[23] and the procedure set forth in Tenn. Comp. R. & Regs. 0720-13-.03[24] and held that HSDA correctly applied a

[23] Tenn. Code Ann. §§ 4-5-315(a)(1) and (d) state:

> (a) The agency upon the agency's motion may, and where provided by federal law or upon appeal by any party shall, review an initial order, except to the extent that:
> (1) A statute or rule of the agency precludes or limits agency review of the initial order;
> ***
> (d) The person reviewing an initial order shall exercise all the decisionmaking power that the agency would have had to render a final order had the agency presided over the hearing, except to the extent that the issues subject to review are limited by rule or statute or by the agency upon notice to all parties.

[24] Tenn. Comp. R. & Regs. 0720-13-.03 states:

> (1) An Initial Order issued by an Administrative Judge, sitting alone, may be reviewed by The Agency pursuant to T.C.A §§4-5-301, et seq., 68-11-1610, these Rules, and the Rules of the Secretary of State Chapter 1360-4-1. The Agency may, in its discretion, decline to exercise any review of an Initial Order issued by an Administrative Judge, in which event the Initial Order issued by an Administrative Judge shall become a Final Order as provided by the Administrative Procedures Act.
> (2) In such a review proceeding, The Agency's review is strictly limited to the record which was developed before the Administrative Judge. No additional evidence is to be received or considered by The Agency.
> (3) Such a review proceeding is in the nature of appellate review. Each party will be given the opportunity to file a brief which should specify what action the party maintains

de novo standard of review. We agree that this was the appropriate standard.

This is a matter of law, which we review *de novo*. *See* Tenn. R. App. P. 13(d); *Davis v. Shelby County Sheriff's Dept.*, 278 S.W.3d 256, 264 (Tenn. 2009).

At the outset, we note the following holding from *McEwen*:

> Tennessee's Uniform Administrative Procedures Act does not require an agency to defer to the fact-finding or legal conclusions in an administrative law judge's initial order. . . . In Tennessee's administrative decision-making hierarchy, like the hierarchy in most states, the agencies remain superior to the hearing officers and administrative judges. An agency's decision-making authority is not circumscribed in any way by an initial order. Because an agency possesses its own fact-finding authority, it may make its own factual determinations, and it may substitute its judgment for that of the hearing officer or administrative judge.

McEwen, 173 S.W.3d at 821-22 (internal citations and footnotes omitted). It is against this interpretation that we consider whether the statement at Tenn. Comp. R. & Regs. 0720-13-.03(3) that the review should be "in the nature of appellate review" imposes a standard of deference to the ALJ's order. We agree with the Chancellor's thorough analysis and holding that 0720-13-.03(3), read in the context with the other provisions of the rule, "does not refer to a deferential standard of review but to the way the proceedings before the Agency are conducted upon reviewing the ALJ's initial order . . . and that the review is limited to the record developed by the ALJ." Such an interpretation of the rule is entirely consistent with the nature of the HSDA's review as an administrative agency as prescribed by Administrative Procedures Act. There is no basis for the deference advocated by Covenant, in the absence of a statute or rule requiring the same.

> The Agency should take on the Initial Order. The Agency may place reasonable page limitations on such briefs.
> (4) In such a review proceeding, each party will normally be limited to oral argument of thirty (30) minutes in length, including rebuttal.
> (5) At the conclusion of the review proceeding The Agency may decide that the Initial Order should be adopted in its entirety, or it may make such modifications to the Initial Order as it deems appropriate.
> (a) Alternatively, The Agency may take the matter under advisement, and subsequently reconvene, after reasonable notice to the parties, to hold its public deliberations and to render a Final Order.

(2) HSDA's Application of Tenn. Code Ann. § 68-11-1609(b)

Covenant contended in the trial court and on appeal that HSDA's decision was arbitrary and capricious because the agency members disregarded the State Health Plan's Guidelines for Growth in making their decision.[25] The Chancellor did not agree, observing as follows in the order:

> By the time the legal and factual issues of the case had been organized, developed, explained and decided by the ALJ on appeal to the Agency, it and the parties did not have to reinvent the wheel. In particular, on July 24, 2013, the Agency voted to limit review of the Initial Order "specifically to examining the criteria of need." TR Vol. 4 at 2628-29. Also narrowing the scope of the Agency review was that all the parties agreed that the LINAC was not supported by the parameters in the Guidelines. Thus, the Agency's focus was narrowed considerably to whether there existed compelling reasons to depart from the Guidelines.

The Chancellor concluded that HSDA's decision did not disregard the Guidelines and that "[i]t was not arbitrary and capricious for the Agency's deliberations to instead analyze reasons outside of the Guidelines to decide if those reasons were sufficiently compelling to vary therefrom."

We agree with the Chancellor's conclusion. The record of the contested case hearing establishes that both parties presented evidence that the linear accelerator, as proposed, did not meet the minimum capacity or population criteria set forth in the Guidelines for Growth and that ETRTS presented evidence to show that, despite its failure to meet those criteria, the linear accelerator was still needed.

HSDA members did not act arbitrarily or capriciously by not explicitly referencing the Guidelines during their deliberations. No party disputed that the criteria set forth in the Guidelines for Growth could not be met by the project, and thus, any discussion of the Guidelines during HSDA's review would have been fruitless. The members were instead focused on whether ETRTS had presented compelling evidence showing a need for the linear accelerator beyond the Guidelines' criteria for establishing need. The record shows that the agency members were familiar with the contested case proceedings, during which the Guidelines for Growth were addressed, and, after briefing and oral argument by the parties, the members asked questions, made comments, voted to overturn the ALJ's order, and then engaged in deliberations over desired changes to the initial order. This review resulted in HSDA's conclusion in its final order that "ETRTS

[25] See discussion at footnote 7, *supra*.

has given several credible and compelling considerations to look beyond the Guidelines for Growth." Covenant concedes that "the HSDA has the authority and discretion to deviate from the State Health Plan," and our review of the statutes and regulations governing the agency do not yield a different result. The court correctly concluded that the agency's review was meaningful and that its decision was neither arbitrary nor capricious.

IV. CONCLUSION

In light of our conclusion that HSDA's decision is supported by substantial and material evidence, we reverse the order denying the CON and remand this case to the trial court for entry of an order affirming the agency decision.

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RICHARD H. DINKINS, JUDGE