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Supreme Court of New Jersey.
COOPER UNIVERSITY HOSPITAL and Our Lady of Lourdes Medical Center, Appellants-Appellants,
v.
Fred M. JACOBS, M.D., J.D., Commissioner of the Department of Health and Senior Services, Respondent-Respondent,
and
Virtua-West Jersey Hospital-Marlton, Intervenor-Respondent,
and
Deborah Heart and Lung Center, Intervenor-Appellant.
Argued March 20, 2007.
Decided May 31, 2007.

Background: Cardiac surgery centers sought review of Department of Health and Senior Services' grant of a certificate of need to hospital to conduct elective angioplasty. The Superior Court, Appellate Division, 2006 WL 3017933, affirmed. Cardiac surgery centers' petitioned for certification.

Holding: Upon grant of certification, the Supreme Court, Stern, J., temporarily assigned, held that demonstration project regarding elective angioplasty did not comply with specific regulations regarding cardiac care.

Reversed and remanded.

West Headnotes

[1] Constitutional Law 92 4025

92 Constitutional Law
92XXVII Due Process
92XXVII(F) Administrative Agencies and Proceedings in General
92k4025 k. In General. Most Cited Cases

Constitutional Law 92 4026

92 Constitutional Law
92XXVII Due Process
92XXVII(F) Administrative Agencies and Proceedings in General
92k4026 k. Rules and Regulations. Most Cited Cases
Administrators must do what they can to structure and confine their discretionary powers through safeguards, standards, principles, and rules in order to satisfy due process and produce reasoned and principled decisions. U.S.C.A. Const.Amend. 14.

[2] Administrative Law and Procedure 15A 416.1

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(C) Rules and Regulations
15Ak416 Effect
15Ak416.1 k. In General. Most Cited Cases
Although an administrative agency may change its regulations, so long as they are in force the agency is bound by them.

[3] Administrative Law and Procedure 15A 416.1

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(C) Rules and Regulations
15Ak416 Effect
15Ak416.1 k. In General. Most Cited Cases
Waivers of regulatory requirements must generally be embodied in a regulation, adopted pursuant to the Administrative Procedure Act (APA), authorizing waivers and establishing appropriate standards for the exercise of waiver authority. N.J.S.A. 52:14B-1 to 52:14B-15.

[4] Administrative Law and Procedure 15A

763

15A Administrative Law and Procedure
15AV Judicial Review of Administrative Decisions
15AV(D) Scope of Review in General
15Ak763 k. Arbitrary, Unreasonable or Capricious Action; Illegality. Most Cited Cases
Administrative action cannot be arbitrary or capricious or inconsistent with the legislative intent, policy, or delegation of authority.

[5] Administrative Law and Procedure 15A 507

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(D) Hearings and Adjudications
15Ak507 k. Report or Opinion; Reasons for Decision. Most Cited Cases
Administrative officers should articulate the standards and principles that govern their discretionary decisions in as much detail as possible.

[6] Health 198H 240

198H Health
198HI Regulation in General
198HI(C) Institutions and Facilities
198Hk236 Licenses, Permits, and Certificates
198Hk240 k. Need, Public Necessity. Most Cited Cases
Demonstration project regarding elective percutaneous transluminal coronary angioplasty (PTCA) in hospitals that did not have on-site cardiac surgery facilities, which project was authorized by the Department of Health and Senior Services under general regulation regarding demonstration projects, was inconsistent with more specific regulations concerning cardiac care, which expressly limited the performance of elective PTCA to those facilities that had on-site cardiac surgery services, and thus, demonstration project could not continue without promulgation of a rule specifically authorizing the demonstration project, reflecting the detail that was necessary to provide for patient care in conducting elective PTCA. N.J.A.C. 8:33-3.11(e), 8:33E-2.3(d)(3), 8:43G-7.28.

[7] Administrative Law and Procedure 15A 416.1

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(C) Rules and Regulations
15Ak416 Effect
15Ak416.1 k. In General. Most Cited Cases
The approval of programs inconsistent with detailed regulations that would otherwise prohibit them cannot stand.

****732** Edwin F. Chociey, Morristown, argued the cause for appellants (Riker, Danzig, Scherer, Hyland & Perretti, attorneys; Glenn A. Clark, of counsel; Mr. Chociey and Mr. Clark, on the briefs).

R. James Kravitz, Lawrenceville, argued the cause for intervenor-appellant (Fox-Rothschild, attorneys; Jonathan D. Weiner, of counsel; Mr. Weiner, Maureen E. Kerns and Abbey True Harris, on the briefs).

Susan J. Dougherty, Deputy Attorney General, argued the cause for respondent (Stuart Rabner, Attorney General of New Jersey, attorney; Michael J. Haas, Assistant Attorney General, of counsel).

Philip H. Lebowitz, Philadelphia, PA, a member of the Pennsylvania bar, argued the cause for intervenor-respondent (Duane Morris, attorneys; ****733**Katherine Benesch , of counsel; Mr. Lebowitz and Erin M. Duffy, on the brief).

Judge STERN (temporarily assigned) delivered the opinion of the Court.

***127** In November 2004, the Department of Health and Senior Services (Department) issued a call inviting health care facilities without a cardiac surgery facility on site to apply for a certificate of

need (CN) to conduct elective angioplasty. The Commissioner of the Department (Commissioner) granted CNs to nine New Jersey community hospitals that responded to the call. One of the hospitals was Virtua-West Jersey Hospital-Marlton (Virtua). Three cardiac surgery centers located in Virtua's general service area-Cooper University Hospital (Cooper), Our Lady of Lourdes Medical Center (Lourdes), and Deborah Heart and Lung Center (Deborah)-challenged the call and the subsequent grant of a CN to Virtua. In an unpublished opinion, the Appellate Division concluded that the Commissioner was authorized to issue the call for the CN as a "demonstration project" pursuant to *N.J.A.C.* 8:33-3.11(e), and that the grant of the CN to Virtua was not arbitrary, capricious, or unreasonable.

***128** We granted the cardiac surgery centers' petitions for certification and now conclude that although *N.J.A.C.* 8:33-3.11(e) authorized the call, the regulation, as applied, violates fundamental principles relating to the regulatory process. We further hold that because Virtua and eight other community hospitals with similar projects, based on CNs issued without challenge, have relied on CNs issued more than a year ago and on subsequent licensure, the projects may continue through November 30, 2007. However, a proper regulation must be promulgated-after appropriate adherence to the principles of rulemaking-before any such "demonstration project" can be continued beyond that date.

I.

The call, published in the New Jersey Register,[FN1] invited hospitals licensed to perform primary percutaneous transluminal coronary angioplasty (PTCA), but not licensed to perform cardiac surgery, to submit CN applications to perform elective PTCA.[FN2] ***129** The call stated that six successful applicants would be granted a CN to participate in the Atlantic C-PORT Trial, Elective Angioplasty Study (Atlantic C-****734** PORT-E), "a planned multi-state demonstration project to test the safety, quality and cost of elective angioplasty offered at community hospitals that do not also offer cardiac surgery services [(CABG) [FN3]] on site." Virtua submitted an application in response to the call. On October 31, 2005, the Commissioner granted CNs to nine hospitals. Five CNs, including the one issued to Virtua, had been among six recommended for approval by the State Health Planning Board (SHPB). The other four had not been recommended by the SHPB. However, the only CN challenged in litigation was the one issued to Virtua.

FN1. *See* "Notice of Invitation for Certificate of Need Applications for Participation in a Demonstration Project Pertaining to Elective Angioplasty Without Back-up Surgery On-Site," 36 *N.J.R.* 4996(b) (Nov. 1, 2004).

FN2. PTCA "means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction." *N.J.A.C.* 8:33E-1.2 (amended in July 2006 to replace the term "PTCA" with " 'Percutaneous coronary intervention (PCI),' " 38 *N.J.R.* 3025(a) (July 17, 2006), to "reflect current clinical terminology," 38 *N.J.R.* 53(a) (Jan. 3, 2006)). As used in the Administrative Code, "PCI [(or PTCA)] also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures." *N.J.A.C.* 8:33E-1.2.

"Primary PTCA" is an emergency PTCA performed during acute myocardial infarction. *N.J.A.C.* 8:33E-1.3(4)(d), *N.J.A.C.* 8:33E-2.3(d)(3). An acute myocardial infarction is "[a] sudden occurrence of an infarction of the muscular wall of the heart, which means death of the muscle resulting from a blockage of the blood supply by a clot,"*Attorneys' Dictionary of Medicine* 2378, Part 1-A

(2005), and is commonly known as a heart attack. MedLine Plus, Medical Encyclopedia, http:// www. nlm. nih. gov/ medlineplus/ ency/ article/ 000195. htm. An "elective PTCA" is a PTCA that is performed on patients at times other than during acute myocardial infarction. *See N.J.A.C.* 8:33E-1.3(4)(d), *N.J.A.C.* 8:33E-2.3(d)(3).

FN3. " 'Coronary artery bypass graft' surgery (CABG) means a surgical procedure to treat narrowing or stenosis of the coronary arteries. The procedure is performed by a cardiothoracic surgeon who creates bypasses around the obstructions in the coronary arteries with arteries or veins from elsewhere in the body to improve blood flow to the heart (that is, revascularization of the myocardium)." *N.J.A.C.* 8:33E-1.2.

Cooper and Lourdes filed an appeal in the Appellate Division challenging the call and the Commissioner's grant of a CN to Virtua. Deborah, which had challenged the call before CNs had been granted, intervened in the action in support of Cooper and Lourdes' position, and Virtua intervened in support of the Commissioner. Appellants argued that the call under *N.J.A.C.* 8:33-3.11(e) was *ultra vires* principally because it authorized as a "demonstration project" a procedure that is expressly prohibited by other regulations. Appellants also asserted that, even if the call was valid, issuance of the CN to Virtua was arbitrary, capricious and unreasonable. The Appellate Division rejected those contentions.

II.

PTCA was first introduced in 1976. During its early use, one in every twenty-five patients, or four percent, on whom the procedure***130** was performed required emergency bypass surgery as a result of complications arising from PTCA. Today, only about one in every five hundred patients, or two-tenths of one percent, requires emergency bypass surgery following PTCA. The decreased risk associated with the procedure has sparked debate within the medical community about the safety of performing PTCA in hospitals without on-site cardiac surgery.

Dr. Thomas Aversano of the Johns Hopkins University School of Medicine devised the Atlantic C-PORT-E study to determine whether it is safe to perform elective PTCA at hospitals where on-site cardiac surgery is unavailable and how it can be done. Dr. Aversano hypothesizes that elective PTCA may be performed at hospitals without on-site cardiac surgery facilities with the same degree of success as at hospitals performing on-site cardiac surgery.

The Atlantic C-PORT-E study expects the participation of forty community hospitals to test approximately 13,200 patients over the course of two to three years. Participating hospitals are required to ask patients who enter those hospitals for diagnostic cardiac catheterizations whether they would like to participate in the study. If a patient qualifies and consents to participate in the study, he or she is scheduled for elective PTCA either at a hospital without on-site cardiac surgery or at a hospital where on-site cardiac surgery is available. Seventy-five percent of participating patients, approximately 9,900 patients, will undergo elective PTCA at a hospital without on-site cardiac surgery. Participating hospitals will collect data from the patients for a period of six months following the elective PTCA, and that data will be compiled****735** in a central database for reporting and evaluation.

At least six states-Alabama, Georgia, Illinois, New Jersey, Ohio, and Pennsylvania-have endorsed and participate in the Atlantic C-PORT-E Study. At least two states-Maryland and Massachusetts-have declined to participate.

The Department's November 2004 call invited qualifying New Jersey hospitals to enroll in the Atlantic

C-PORT-E Study. 36 ***131** *N.J.R.* 4996(b) (Nov. 1, 2004). According to the call, the purpose of the demonstration project was to "facilitate scientifically rigorous collection and analysis of data that will contribute significantly to the evidence base nationally on the issue of the comparative safety and efficacy of elective angioplasty in hospitals with and without on-site [CABG] surgical back-up." The call stated that it was being "issued in accordance with" *N.J.S.A.* 26:2H-7, *N.J.A.C.* 8:33, *N.J.A.C.* 8:33-3.11(e), and *N.J.A.C.* 8:43G.

The call set forth three requirements for eligibility, limiting participation to hospitals: (1) "not currently licensed to perform cardiac surgery[,]" but (2) "licensed to provide primary PTCA services," or holding or applying for a CN to do so, (3) that "have signed agreements with New Jersey-licensed cardiac surgery center(s) indicating they are willing to participate in Atlantic C-PORT-E."

The call required applicants to comply with "the Certificate of Need Application and Review Process" outlined in *N.J.A.C.* 8:33, and specifically to "submit documentation in accordance with *N.J.A.C.* 8:33-3.11(e)." Applicants were required to document how they would: (1) satisfy the "study site inclusion criteria specified in the protocol for Atlantic C-PORT-E Study"; (2) fulfill various "interventional cardiologist inclusion criteria"; (3) comply with the "patient selection criteria specified in the Atlantic C-PORT-E Study protocol"; (4) obtain "[a]pproval of the study protocol by the applicant's Institutional Review Board"; (5) achieve "the [t]arget volume specified in the Atlantic C-PORT-E Study protocol of elective angioplasties performed at the applicant's site"; and (6) implement "[p]erformance of primary PTCA in accordance with *N.J.A.C.* 8:33E-2.16."

The call further stated that the Department would consider specific criteria in reviewing each CN application, including: "ability to offer a high quality program; representation of the State's diverse regions and urban/suburban/rural populations; potential to increase access to care for minorities and the medically underserved; and projected demonstration project elective angioplasty ***132** case volume." According to the call, the Department would approve "[a] maximum of six applications." Those hospitals whose CN applications were granted and were then accepted for participation in the study would receive demonstration licenses to perform "elective angioplasty [ ] on patients who [gave] informed consent to participate in the trial and who" are chosen to participate using Atlantic C-PORT-E's protocol. The licenses were to be "issued for a period not to exceed three years, and [would] be annually renewable during the three-year period."

In January 2005, Virtua, a non-profit organization that serves patients in Burlington, Camden, and Gloucester Counties, submitted an application in response to the call. Virtua's application stated that it had been approved to provide primary PTCA services and would commence performing those services by February 2005. It projected that, if granted a license to perform elective PTCA procedures, it would perform approximately 227 of those procedures during its first year. The other ****736** institutions currently providing elective PTCA in Virtua's general service area are Cooper, Deborah, Lourdes and Atlantic City Medical Center-Mainland.

Virtua's application included a copy of a letter from Atlantic City Medical Center memorializing its commitment to participate as Virtua's partner "as the on-site surgery center," in Atlantic C-PORT-E. Also included in Virtua's application was a copy of a contract between Virtua and Lourdes for the transfer of patients who require cardiac surgery and a copy of a contract between Virtua and Exceptional Medical Transportation providing for the transportation of patients to and from Virtua.

In summarizing its application, Virtua stated that it had documented "strong evidence [of its] ability to provide high quality cardiac services to medically underserved populations throughout a region of New Jersey that presently has limited access to elective angioplasty."

The SHPB analyzed each application based on the criteria listed in the call and recommended that licenses to perform elective ***133** PTCA without on-site cardiac surgery be granted, with conditions, to six of the eighteen applicants. One of them was Virtua.

The SHPB provided three reasons for recommending a grant of a CN to Virtua. First, Virtua was "the only demonstration applicant ... located within the seven southernmost counties in New Jersey, which have fewer primary and elective angioplasty providers per capita than hospitals located in Northern and Central New Jersey regions." Second, Virtua "provided the sixth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants" in 2003 and 2004, leading the SHPB to conclude that Virtua could potentially perform the requisite two hundred elective PTCA procedures during its first year. Finally, the SHPB determined that Virtua had "satisfied all other pertinent criteria."

The same day it issued its recommendations, the SHPB held a formal meeting and heard public commentary about the CN applications and Atlantic C-PORT-E. Dr. Aversano, the architect of the Atlantic C-PORT-E Study, attended and spoke at the meeting. Among other public commentators who spoke during the meeting were representatives from Cooper, Deborah, Lourdes and Virtua. The representative from Lourdes specifically opposed Virtua being granted a license to perform elective PTCA. The representatives from Deborah and Cooper expressed concern about licensing any facility without on-site cardiac surgery to perform elective PTCA. The representative from Virtua spoke in support of Virtua's application for a CN.

On October 31, 2005, the Commissioner approved the applications of nine hospitals-five hospitals recommended by the SHPB and four hospitals not recommended by the SHPB. The Commissioner believed that increasing the number of participating New Jersey hospitals from six to nine would increase the effectiveness of the Atlantic C-PORT-E Study. The Commissioner deviated from the SHPB's specific recommendations, in part, because he believed that those recommendations did not insure sufficient representation of all of New Jersey's diverse regions in the ***134** demonstration project. In granting a CN to Virtua, the Commissioner reiterated the SHPB's finding that Virtua was the only applicant "located within the seven southernmost counties in New Jersey."

The Appellate Division rejected the contentions of appellants and intervenor-Deborah directed to the regulation, the call, and the issuance of a CN to Virtua. The panel held that the call was for a valid ****737** demonstration project and that the Commissioner's grant of a CN to Virtua was not arbitrary, capricious, or unreasonable. The panel recognized that the Department's regulations prohibit the performance of elective PTCA at hospitals without on-site cardiac surgery facilities, but accepted the Commissioner's argument that *N.J.A.C.* 8:33-3.11(e) nevertheless authorizes calls for demonstration projects that do not comply with other regulations. As such, the Appellate Division concluded that the Legislature vested the Commissioner with broad powers, including the power to create demonstration projects pursuant to *N.J.A.C.* 8:33-3.11(e), and that

> [t]he question of whether to participate in a broad-based experimental venture in the health care area, fielded under respected and respectable auspices, and designed to develop better understandings of whether and how certain health services can be delivered differently, with appropriate assurances of safety and efficacy, is manifestly a decision so impacted by professional expertise as to call for our deference. As long as the public health and the interests of competing entities have been protected by a fair application of the Legislature's expressed safeguard, the CN process, it is not our place to substitute our judgment for that of the agency charged with regulating the subject matter area.

In affirming the Commissioner's decision to grant

Virtua a CN to participate in the demonstration project, the panel did not discuss the factual merits of Virtua's application or the Commissioner's approval of that application.

We granted certification, 189 *N.J.* 429, 915 *A.*2d 1051 (2007), and accelerated the appeal.[FN4]

FN4. As a result of the accelerated calendaring of the appeal for argument before many applications for amicus participation were received, we denied all such applications.

***135** III.

Cooper and Lourdes challenge the governing regulation, *N.J.A.C.* 8:33-3.11(e), the call, and the Commissioner's approval of Virtua's CN application on several grounds. First, they contend that Virtua's application did not satisfy the CN requirements enumerated in *N.J.S.A.* 26:2H-8 and appropriate regulations. They further assert that the Commissioner did not set forth adequate reasons supporting his approval of Virtua's application and that permitting Virtua to perform elective PTCA will result in significant harm to them and to the public. Additionally, Cooper and Lourdes, along with intervenor Deborah, contend that the call was *ultra vires.* They assert that permitting community hospitals to perform elective PTCA without on-site cardiac surgery contravenes existing health care regulations and thus violates the statutory requirement that the Commissioner must promulgate regulations only with the approval of the Health Care Administration Board (HCAB).

In response, the Commissioner asserts that *N.J.A.C.* 8:33-3.11(e) is valid, the call was not "*ultra vires,*" and the CN was issued for a valid "demonstration project." Specifically, the Commissioner contends that the call constituted an appropriate exercise of agency authority, because the performance of elective PTCA at hospitals without on-site cardiac surgery is a "health care service" currently unavailable in New Jersey and thus the proper subject of a demonstration project and study to determine the need therefor. The Commissioner states that *N.J.A.C.* 8:33-3.11(e) was promulgated to permit precisely the type of demonstration project at issue in this case and will allow evaluation of whether the regulations governing elective ****738**angioplasty should be amended. The Commissioner highlights the public commentary surrounding the adoption of *N.J.A.C.* 8:33-3.11(e), in which the Department expressly acknowledged that the performance of elective PTCA at hospitals without on-site cardiac surgery would be a valid demonstration project. The Commissioner rejects the ***136** contentions that the demonstration project "targets" minorities and the poor and that it is an improper research project.

The Commissioner also argues that his approval of Virtua's CN application was not arbitrary, capricious, or unreasonable, because Virtua's inclusion in the demonstration project is necessary to represent the State's diverse regions, as it is the only applicant from southern New Jersey. The Commissioner further rejects the arguments of Cooper and Lourdes that they will be negatively impacted by Virtua's participation in the project and asserts that any impact on Cooper and Lourdes will be minimal. Finally, the Commissioner contends that the claims of increased mortality rates in patients who receive elective PTCA at hospitals without on-site cardiac surgery are not supported by the evidence.

Virtua agrees that the Appellate Division properly determined that the Commissioner did not exceed his authority in issuing the call, and the Commissioner's issuance of the CN was not arbitrary, capricious, or unreasonable.

IV.

It is the declared public policy of New Jersey "that hospital and related health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost

are of vital concern to the public health." *N.J.S.A.* 26:2H-1. Accordingly, in 1971, the Legislature enacted the Health Care Facilities Planning Act (HCFPA), *N.J.S.A.* 26:2H-1 to -26, to decrease the cost of hospital care in the State. *Saint Peter's Univ. Hosp. v. Lacy,* 185 *N.J.* 1, 5, 878 *A.*2d 829 (2005). The Act gives the Department "central responsibility for the development and administration of the State's policy with respect to health planning, hospital and related health care services and health care facilities cost containment programs [.]" *N.J.S.A.* 26:2H-1.

To achieve its cost-containment purpose, the HCFPA provides that "[n]o health care facility shall be constructed or expanded, and no new health care service shall be instituted ... except upon application for and receipt of a certificate of need[.]" ***137***N.J.S.A.* 26:2H-7. Any service that "is the subject of a health planning regulation adopted by the Department" is considered to be a "health care service" under the HCFPA. *N.J.S.A.* 26:2H-7; *see also N.J.S.A.* 26:2H-2(b) (defining "health care service"). *But see N.J.S.A.* 26:2H-7a,-7c (exempting certain services from the CN requirement). As such, a hospital wishing to institute a new health care service must submit a CN application to the Department. *N.J.S.A.* 26:2H-10. The application is then reviewed by the SHPB, which in turn makes "recommendations" to the Commissioner. *N.J.S.A.* 26:2H-5.8(b). The Commissioner is vested with the authority to "approve or deny an application for a[CN]." Certificates "shall be issued by the [C]ommissioner in accordance with the provisions of [the HCFPA] and based upon criteria and standards therefor promulgated by the [C]ommissioner." *N.J.S.A.* 26:2H-9.

The HCFPA enumerates the criteria the Commissioner must consider before issuing a CN:

> [n]o certificate of need shall be issued unless the action proposed in the application for such certificate is necessary to ****739*** provide required health care in the area to be served, can be economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of health care services in the region or Statewide, and will contribute to the orderly development of adequate and effective health care services. In making such determinations there shall be taken into consideration (a) the availability of facilities or services which may serve as alternatives or substitutes, (b) the need for special equipment and services in the area, (c) the possible economies and improvement in services to be anticipated from the operation of joint central services, (d) the adequacy of financial resources and sources of present and future revenues, (e) the availability of sufficient manpower in the several professional disciplines, and (f) such other factors as may be established by regulation.
>
> [*N.J.S.A.* 26:2H-8.]

If the Commissioner denies an application for a CN, the applicant may request a hearing pursuant to the Administrative Procedure Act (APA), *N.J.S.A.* 52:14B-1 to -25. *N.J.S.A.* 26:2H-9.

The Legislature has authorized the Commissioner to promulgate rules and regulations to effectuate the provisions of the HCFPA. *N.J.S.A.* 26:2H-5(b). However, those regulations must be promulgated in accordance with the APA and require "approval ****138*** of" the HCAB. *N.J.S.A.* 26:2H-5(b); *N.J.S.A.* 26:2H-2(d). The HCAB is comprised of thirteen members: the Commissioner together with the Commissioner of Insurance, "or their designated representatives," and eleven "representative[s] of medical and health care facilities and services, labor, industry and the public at large" who are "appointed by the Governor with the advice and consent of the Senate." *N.J.S.A.* 26:2H-4. The Chair of the HCAB also serves as an *ex officio* member of the SHPB along with the Chair of the Public Health Council, or their designees, and "nine public members appointed by the Governor with the advice and consent of the Senate." *N.J.S.A.* 26:2H-5.7. The Commissioner and the Commissioners of Children and Families and of Human Services are *ex officio* members of the SHPB. *Ibid.*

The health care regulations adopted by the Commissioner and HCAB provide for the hospital licensing standards in Chapter 43G of Title 8 of the New Jersey Administrative Code. Chapter 33E of Title 8 governs certificates of need for "cardiac diagnostic facilities and cardiac surgery centers."

N.J.A.C. 8:43G-7.28 provides that PTCA is to "be performed only in cardiac surgical centers approved by the New Jersey State Department of Health." A "[c]ardiac surgery center" is defined as "a facility capable of providing invasive diagnostic catheterization, and all treatment modalities including open and closed heart surgical procedures." *N.J.A.C.* 8:43G-7.1(b).

The regulations expressly limit the performance of elective PTCA to those facilities that have an on-site operating room. *N.J.A.C.* 8:43G-7.31; *see also* *N.J.A.C.* 8:33E-2.3(d)(3) ("Elective PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site."). However, general hospitals with licensed "full service adult diagnostic cardiac catheterization program[s]" are permitted to apply for a CN to perform primary PTCA without on-site cardiac surgery. *N.J.A.C.* 8:33E-2.16(a)(1); *see* *N.J.A.C.* 8:33E-2.3(d)(3). The hospital applying for the CN must, among other ***139** things, provide evidence of a transfer agreement with a nearby hospital****740** that has on-site cardiac surgery. *See* *N.J.A.C.* 8:33E-2.16(b)(1).[FN5]

FN5. *N.J.A.C.* 8:33-2.1 to -2.16 regulates regional cardiac surgery centers. There is no dispute that the regulations so read at all relevant times.

The regulations also permit the Commissioner to issue CNs to hospitals wishing to participate in "demonstration projects." *N.J.A.C.* 8:33-3.11. A demonstration project is a "health care service, technology, equipment or modality not currently available in the State or which targets unique institutional circumstances or the needs of underserved populations." *N.J.A.C.* 8:33-1.3. The regulations identify two specific types of "demonstration projects"-an "inner city cardiac satellite demonstration project" and "bloodless surgery demonstration projects." *N.J.A.C.* 8:33-3.11(c) & (d). The regulations also contain a broad provision allowing for the granting of CNs for demonstration projects "not specifically identified" in the regulations. *N.J.A.C.* 8:33-3.11(e).

The issues before us require focus on *N.J.A.C.* 8:33-3.11(e). Calls for "demonstration projects" pursuant to *N.J.A.C.* 8:33-3.11(e) are subject to several procedural requirements. First, the call must be published at least "45 days prior to the date the application is required to be filed." *N.J.A.C.* 8:33-3.11(e)(1). Second, each CN application submitted in response to the call must contain specific documentation concerning "exactly what is proposed to be demonstrated[,]""[p]atient care policies ... including criteria for inclusion/exclusion in the demonstration[,]""[p]roposed staff and staff qualifications for the demonstration[,]""[w]ritten documentation that otherwise eligible patients will be accepted into the demonstration regardless of ability to pay[,]""documentation of what data will be collected to evaluate the demonstration project[,]" and "[w]ritten assurances that all [such] data ... shall be reported to the Department." *N.J.A.C.* 8:33-3.11(e)(2). Third, the SHPB must review each application that involves something that ordinarily would require a CN. *N.J.A.C.* 8:33-3.11(e)(3). ***140** The demonstration projects are to be "approved for a period not to exceed two years unless otherwise specified in the call notice." *N.J.A.C.* 8:33-3.11(e)(4).[FN6] Those applicants who are granted a CN "receive licensure approval from the Department to operate the service for the time period specified in the call notice plus the evaluation period specified by the Department ..., provided all applicable licensure standards are met." *N.J.A.C.* 8:33-3.11(e)(5).

FN6. Pursuant to the call, "[r]enewal of the demonstration license during the three-year period will be based on ongoing compli-

ance with all applicable licensure criteria" and other factors. Moreover, "demonstration licenses issued in connection with this study will be terminated no later than 30 days after Atlantic C-PORT-E is halted." 36 *N.J.R.* 4996(b) (Nov. 1, 2004).

In addition to the general criteria set forth in *N.J.S.A.* 26:2H-8, the regulations set forth a review procedure for CN applications, which applies to demonstration projects conducted pursuant to *N.J.A.C.* 8:33-3.11. *See N.J.A.C.* 8:33-4.1 to -4.16. The Department determines whether the application is complete, and if so, it refers the application to the SHPB for review. *N.J.A.C.* 8:33-4.5(a). The SHPB reviews the application and makes a written recommendation to the Commissioner. *N.J.A.C.* 8:33-4.13(a). The Commissioner then determines whether to approve or deny the application. *N.J.A.C.* 8:33-4.15(a). Consistent with *N.J.S.A.* 26:2H-9, if an application is denied, "the applicant may request a hearing pursuant to the [APA]." *N.J.A.C.* 8:33-4.15(b).

****741** V.

We have long recognized that courts are obligated to "give substantial deference to the interpretation an agency gives to a statute that the agency is charged with enforcing." *Saint Peter's Univ. Hosp., supra,* 185 *N.J.* at 15, 878 *A.*2d 829 (quoting *Smith v. Dir., Div. of Taxation,* 108 *N.J.* 19, 25-26, 527 *A.*2d 843 (1987)). However, we have also emphasized that a rule promulgated by the Commissioner and HCAB will be set aside if it is inconsistent with the HCFPA. *See Smith, supra,* 108 *N.J.* at 26, 527 *A.*2d 843; *see also In re N.J. Individual Health Coverage Program's Readoption* ***141** *of N.J.A.C. 11:20-1, et seq.* (*In re N.J. IHCP*), 179 *N.J.* 570, 579, 847 *A.*2d 552 (2004). As we recently said in upholding regulations that dispensed with the CN process with respect to perinatal centers:

[w]e start with the premise that we must give great deference to an agency's interpretation and implementation of its rules enforcing the statutes for which it is responsible. Such deference is appropriate because it recognizes that "agencies have the specialized expertise necessary to enact regulations dealing with technical matters and are 'particularly well equipped to read ... and to evaluate the factual and technical issues that ... rulemaking would invite.' " Consequently, agency rules are accorded a presumption of validity and reasonableness, and the challenging party has the burden of proving the rule is at odds with the statute.

Despite that deference, a rule will be set aside if it is "inconsistent with the statute it purports to interpret." That is, the agency "may not under the guise of interpretation ... give the statute any greater effect than its language allows." Thus, if the regulation is plainly at odds with the statute, we must set it aside.

[*Saint Peter's Univ. Hospital, supra,* 185 *N.J.* at 13, 878 *A.*2d 829 (quoting *In re Freshwater Wetlands Prot. Act Rules,* 180 *N.J.* 478, 488-89, 852 *A.*2d 1083 (2004) (citations omitted)).]

In this case, there is no statutory provision with which the regulations are expressly inconsistent. No statute precludes demonstration projects or the conduct of elective angioplasty at a hospital that does not perform cardiac surgery.

With these principles in mind, we must decide whether the Commissioner is correct in his contention that the call was properly authorized as a demonstration project pursuant to *N.J.A.C.* 8:33-3.11(e).

The administrative history of *N.J.A.C.* 8:33-3.11(e) makes clear that the Commissioner and HCAB contemplated that elective PTCA at a hospital without an on-site surgery facility might be authorized as a demonstration project. In 2002, the Commissioner and HCAB revised the regulations regarding the CN application and review process. *See* 34 *N.J.R.*

458(a) (Jan. 22, 2002); 34 *N.J.R.* 2814(a) (August 5, 2002). The new regulations implemented revisions that, among other things, reflected a trend toward deregulation of certain health care services. *See* 34 *N.J.R.* 458(a) (Jan. 22, 2002). *N.J.A.C.* 8:33-3.11(e) was promulgated as part of those revisions. *Id.* at 475.

***142** During the public commentary period, several hospitals, including Deborah, opposed the proposed adoption of *N.J.A.C.* 8:33-3.11(e). *See* 34 *N.J.R.* 2814-16 (Aug. 5, 2002). Commentators opined that *N.J.A.C.* 8:33-3.11(e) would "subvert[ ] the public hearing process and opportunity for comment that accompanied the adoption of standards for the cardiac demonstration projects specified at *N.J.A.C.* 8:33-3.11(c) and (d) [,]" because amendments of the regulations would not be necessary to implement a project that conflicted with existing ****742** regulations. 34 *N.J.R.* 2815 (Aug. 5, 2002). In other words, a demonstration project could be approved without further rulemaking even if inconsistent with the existing rules. *Ibid.* Deborah suggested, among other things, that the proposed *N.J.A.C.* 8:33-3.11(e) be amended to prohibit the Commissioner from calling for demonstration projects involving cardiac services without first promulgating regulations to govern those demonstration projects. *Ibid.* Prophetically, Meridian Health System expressed concern that "elective angioplasty without on-site surgery back-up" could be the subject of a demonstration project under *N.J.A.C.* 8:33-3.11(e). 34 *N.J.R.* 2815 (Aug. 5, 2002).

The Commissioner expressly acknowledged the adverse commentary but declined to make any changes to the proposed version of *N.J.A.C.* 8:33-3.11(e). 34 *N.J.R.* 2816 (Aug. 5, 2002). The Commissioner also attempted to ameliorate the commentators' concerns by emphasizing that applications to participate in demonstration projects pursuant to *N.J.A.C.* 8:33-3.11(e) would be subject to review by the SHPB before issuance of a CN and that interested parties would be given "an opportunity for public input and review." 34 *N.J.R.* 2816 (Aug. 5, 2002). In specifically addressing Meridian Health System's comment regarding the performance of elective angioplasty at hospitals without on-site cardiac surgery, the Commissioner stated that "any demonstration project involving a service subject to [a CN] would require full, not expedited, review and would include SHPB review." *Ibid.* It appears, therefore, that the Commissioner's contention is correct that, when *N.J.A.C.* 8:33-3.11(e) was adopted, the Commissioner ***143** and HCAB contemplated that the regulation would permit the Commissioner to issue a call for a demonstration project permitting hospitals without on-site cardiac surgery to perform elective angioplasty notwithstanding other existing regulations.

[1][2][3][4][5] The regulation's authorization of the Commissioner's approval cannot end the inquiry before us, however, because adherence to due process has always been integral to the regulatory process. Even before adoption of the Administrative Procedure Act, we emphasized that "[w]ithout sufficiently definite regulations and standards administrative control lacks the essential quality of fairly predictable decisions." *Boller Beverages, Inc. v. Davis,* 38 *N.J.* 138, 152, 183 *A.*2d 64 (1962). "[A]dministrators must do what they can to structure and confine their discretionary powers through safeguards, standards, principles and rules" in order to satisfy due process and produce reasoned and principled decisions. *Crema v. N.J. Dep't of Envtl. Prot.,* 94 *N.J.* 286, 301, 463 *A.*2d 910 (1983) (quoting *City of Santa Clara v. Kleppe,* 418 *F.Supp.* 1243, 1261 (N.D.Cal.1976)). Moreover, "although an administrative agency may change its regulations, so long as they are in force the agency is bound by them." *County of Hudson v. Dep't of Corrs.,* 152 *N.J.* 60, 71, 703 *A.*2d 268 (1997) (per curiam); *see also Iuppo v. Burke,* 162 *N.J.Super.* 538, 551-52, 394 *A.*2d 96 (App.Div.), *certif. denied,* 79 *N.J.* 462, 401 *A.*2d 219 (1978). Waivers of regulatory requirements must generally be embodied in a regulation, adopted pursuant to the APA, "authorizing waivers and establishing appropriate standards for the exercise of waiver authority."

SMB Assocs. v. N.J. Dep't of Envtl. Prot., 264 *N.J.Super.* 38, 50, 624 *A.*2d 14 (App.Div.1993), *aff'd,* 137 *N.J.* 58, 644 *A.*2d 558 (1994). *See also In re CAFRA Permit No. 87-0959-5 Issued to Gateway Assocs.,* 152 *N.J.* 287, 308, 704 *A.*2d 1261 (1997) ("an agency that seeks the power to waive its substantive regulations should adopt a regulation pertaining****743** to any such waiver and setting forth appropriate standards to govern agency decision-making"). Furthermore, it is well settled that administrative action cannot be arbitrary or capricious or inconsistent ***144** with the legislative intent, policy, or delegation of authority. *In re N.J. IHCP, supra,* 179 *N.J.* at 579, 847 *A.*2d 552; *George Harms Constr. Co., Inc. v. N.J. Turnpike Auth.,* 137 *N.J.* 8, 27, 644 *A.*2d 76 (1994). As such, "administrative officers [should] articulate the standards and principles that govern their discretionary decisions in as much detail as possible." *Crema, supra,* 94 *N.J.* at 301, 463 *A.*2d 910 (internal citation omitted).

[6] *N.J.A.C.* 8:33-3.11(e), under which the project was approved, is considerably broader and less detailed than *N.J.A.C.* 8:33-3.11(c) and (d), regulations that explicitly authorize other demonstration projects by incorporating medical prerequisites and other specific requirements for those projects. The need for such detail flows from the health concerns involved. Moreover, like the others involved in the Atlantic C-PORT-E study, the Virtua CN authorized a medical procedure that is prohibited by or unauthorized in, and inconsistent with, the Administrative Code's more specific regulations concerning cardiac care. *See N.J.A.C.* 8:33E-2.3(d)(3); *N.J.A.C.* 8:43G-7.28 to -7.31. In fact, the authorizing regulation itself requires compliance with "all applicable licensure standards[,]" *N.J.A.C.* 8:33-3.11(e)(5), when no licensure would otherwise be permitted for such a project.[FN7] Furthermore, the involvement of the SHPB cannot be the basis for sustaining the call, as the Commissioner and Virtua contend, because its role is merely advisory, and it does not approve the grant. *See N.J.A.C.* 8:33-4.13(c).[FN8] The decision maker under both the statute and regulation is the Commissioner alone, *see N.J.S.A.* 26:2H-9; ***145** *N.J.A.C.* 8:33-4.15, as demonstrated in this case where the SHPB recommended the grant of only five of the nine CNs approved.

FN7. In his brief before the Appellate Division with respect to *N.J.A.C.* 8:33-3.11(e)(5), the Commissioner says only that the regulation "cannot be reasonably read to require that a demonstration project comply with those licensure standards that prohibit the very service that is the subject of the demonstration project." The lack of clarity of *N.J.A.C.* 8:33-3.11(e)(5) supports our holding that the regulation is invalid in terms of application to the call, Atlantic C-PORT-E, and the CN issued to Virtua.

FN8. As to the role of the SHPB, related to costs and economic containment, *see N.J.S.A.* 26:2H-2(p), -6.1(h).

Finally, there is no dispute that, independent of the "demonstration project," the Commissioner could not approve the conduct of elective angioplasty in a facility without an on-site cardiac surgical center. To the contrary, it is well established that rulemaking would be required to permit authorization of the procedure. *See Metromedia Inc. v. Dir., Div. of Taxation,* 97 *N.J.* 313, 328-37, 478 *A.*2d 742 (1984). Yet here, by calling the C-PORT-E study a "demonstration project," the Commissioner has authorized adoption of a medical procedure that has not otherwise been authorized by rulemaking. In so doing, he also decided for himself to authorize more CNs than announced in the call and included hospitals not recommended by the SHPB. Notwithstanding *N.J.A.C.* 8:33-3.11(e), the issuance of CNs incident to the Atlantic C-PORT-E study is the equivalent of a waiver without adequate standards. The fact that the Commissioner could decide for himself to issue the call for a demonstration project without any established medical criteria, determine how many CNs to issue, and choose the facilities to

which they should be issued, ****744** emphasizes the need for proper rulemaking. In any event, in this case, the Commissioner has issued a CN based on a "demonstration project" that is inconsistent with the detailed regulations concerning PTCA.

Under the circumstances, we cannot sustain the grant of CNs for the Atlantic C-PORT-E study.[FN9]

> FN9. We do not address any other type of demonstration project and do not otherwise address the validity of *N.J.A.C.* 8:33-3.11(e) in terms of authorizing other types of demonstration projects that do not conflict with existing regulations.

VI.

As stated at the outset, nine CNs were issued, but only the one issued to Virtua was challenged, and a stay of its grant was ***146** denied. Despite the challenge to the call, eight other facilities have been operating, or moving towards licensure, without challenge to their respective CNs. The facilities have invested significant time and resources in implementing their respective demonstration projects, and we must assume that they have relied in good faith on the approved CNs in going forward with staffing and resource allocation as well as patient care. It would therefore be unjust and inappropriate to summarily terminate the demonstration projects. *See Lance v. McGreevey,* 180 *N.J.* 590, 599, 853 *A.*2d 856 (2004) (per curiam) (prospectively applying a decision determining State use of anticipated revenues from bond sales to balance budget unconstitutional); *County of Hudson, supra,* 152 *N.J.* at 74, 703 *A.*2d 268 (staying a portion of a decision for sixty days that requires the Department of Corrections to comply with its own juvenile prisoner transfer regulation); *Salorio v. Glaser,* 93 *N.J.* 447, 462, 467-69, 461 *A.*2d 1100 (1983) (prospectively declaring Emergency Transportation Tax unconstitutional but refusing to order retroactive reimbursements).

[7] On the other hand, if the program is to continue, concerns both for the process and for patient well-being require that a specific regulation be promulgated to authorize continuation of the demonstration project and participation in Atlantic C-PORT-E. The approval of programs inconsistent with detailed regulations that would otherwise prohibit them cannot stand. *See County of Hudson, supra,* 152 *N.J.* at 70-71, 703 *A.*2d 268. The more specific regulations concerning the other demonstration projects authorized by regulation relating to bloodless surgery and inner-city care reflect detail that is necessary to provide for patient care in conducting elective angioplasty. *See N.J.A.C.* 8:33-3.11(c) & (d). In respect to this demonstration project, the regulation must do the same, particularly because concerns for patient safety previously resulted in regulations prohibiting exactly what this demonstration project permits.

Accordingly, New Jersey's participation in the Atlantic C-PORT-E study must cease on November 30, 2007, unless ***147***N.J.A.C.* 8:33-3.11 is amended, consistent with the procedure in the APA, to remedy the present inadequacies in the demonstration project authorization. Likewise, the previously issued CNs and licenses must be reissued in conformity with a new or amended regulation.

The judgment of the Appellate Division is reversed, and the matter is remanded to the Commissioner of the Department of Health and Senior Services for further proceedings consistent with this opinion.

For reversal and remandment-Chief Justice ZAZZALI, and Justices LaVECCHIA, ALBIN, STERN (t/a), CUFF (t/a)-5.
****745** *Not Participating*-Justices LONG, WALLACE, RIVERA-SOTO, HOENS-4.
Opposed-None.
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