COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT

SOUTHCOAST HOSPITALS GROUP, INC.,

Plaintiff,

v.

THE MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH,
MONICA BHAREL, M.D., in her capacity as Commissioner of the Massachusetts Department of Public Health,
STEWARD ST. ANNE'S HOSPITAL CORPORATION, and
STEWARD HEALTH CARE SYSTEM, LLC,

Defendants.

CIVIL ACTION NO.

VERIFIED COMPLAINT
FOR DECLARATORY AND INJUNCTIVE RELIEF

NATURE OF THE ACTION

1. This is an action for declaratory and injunctive relief by Southcoast Hospitals Group, Inc. ("Southcoast") arising from the effort by defendant Steward St. Anne's Hospital Corporation ("Steward St. Anne's") to obtain authorization to provide cardiac catheterization services at St. Anne's Hospital ("St. Anne's") in Fall River pursuant to a "Circular" published by the Massachusetts Department of Public Health ("DPH").

2. In 2008, DPH established a moratorium on accepting applications for new cardiac catheterization services for hospitals located within 30 minutes' travel time (via emergency

ambulance) of a hospital that currently provides primary angioplasty 24 hours per day, seven days a week.

3. The Circular, published by DPH in July 2014 at the behest of and after receiving written comments from defendant Steward Health Care System, LLC ("Steward Health Care"), creates an exception to that moratorium. It permits an Accountable Care Organization ("ACO"), such as Steward Health Care, to transfer "the license" for cardiac catheterization services from a hospital in its system that is not performing the minimum required number of procedures to another hospital in its system, even if the new hospital would otherwise be barred by the moratorium from offering new cardiac catheterization services (the "ACO Exception Circular").

4. In 2014, Steward Health Care owned and operated as part of its ACO, Quincy Medical Center ("QMC"), a hospital in Quincy, Massachusetts that had an underperforming cardiac catheterization service, as well as Steward St. Anne's .

5. Relying upon the ACO Exception Circular, Steward Health Care seeks to transfer the cardiac catheterization service from QMC, which closed in December 2014, to St. Anne's.

6. Upon information and belief, DPH will imminently approve the transfer of a "service license" to provide cardiac catheterization services to Steward St. Anne's, which is located less than two miles from Southcoast's Charlton Memorial campus in Fall River, and less than 15 miles from its St. Luke's campus in New Bedford. Charlton Memorial provides primary angioplasty services 24 hours per day, seven days a week. St. Luke's does not provide primary angioplasty services but does perform diagnostic cardiac catheterization.

7. Southcoast seeks a declaration that DPH may not approve, and Steward St. Anne's may not establish and operate, a cardiac catheterization service at St. Anne's hospital pursuant to the Circular, for at least two reasons:

A. First, the ACO Exception Circular constituted a non-interpretive regulation amending DPH's cardiac catheterization licensure regulations and was issued by DPH without complying with the Administrative Procedure Act or obtaining the approval of the DPH Public Health Council as required by M.G.L. c. 111, § 3, and, as such, is unenforceable; and

B. Second, even if the ACO Exception Circular were enforceable, the cardiac catheterization service Steward Health Care seeks to transfer to its subsidiary, Steward St. Anne's, does not meet the requirements of the ACO Exception Circular because the service to be "transferred" has no legal existence apart from QMC's license, which license (i) QMC relinquished upon the permanent closure of the hospital in December 2014; and (ii) expired by its terms on September 30, 2015, at the latest.

8. To avoid irreparable harm to Southcoast and harm to the public arising from Steward St. Anne's opening a cardiac catheterization service during the pendency of this action, Southcoast seeks, after notice and a hearing, an order enjoining (a) DPH and Monica Bharel, M.D., in her capacity as Commissioner of DPH, from authorizing or approving Steward St. Anne's establishment of a cardiac catheterization service at St. Anne's, and (b) Steward St. Anne's from operating a cardiac catheterization service at St. Anne's.

PARTIES

9. Plaintiff, Southcoast, is a tax-exempt Massachusetts non-profit Public Charitable corporation with a principal place of business at 101 Page Street, New Bedford, Massachusetts 02740.

10. Defendant, DPH, is a duly organized state agency in the Commonwealth's Executive Office of Health and Human Services ("EOHHS") under G.L. c. 6A, § 16, with a principal place of business at 250 Washington Street, Boston, Suffolk County, Massachusetts 02108.

11. Defendant, Monica Bharel, M.D., is the Commissioner of DPH, with a principal place of business at 250 Washington Street, Boston, Suffolk County, Massachusetts 02108.

12. Defendant, Steward St. Anne's, is a Delaware corporation with a principal place of business at 500 Boylston Street, 5th Floor, Boston, MA 02116.

13. Defendant, Steward Health Care, is a Delaware corporation with a principal place of business at 500 Boylston Street, 5th Floor, Boston, MA 02116.

JURISDICTION AND VENUE

14. This Court has jurisdiction over this action pursuant to G.L. c. 231A.

15. Under G.L. c. 214, § 5 and c. 223, § 1, venue is proper in this County because the defendants are located in Suffolk County, Massachusetts.

FACTS

Southcoast
and Steward St. Anne's

16. Southcoast holds a license from DPH to operate hospital campuses at three locations: Charlton Memorial Hospital in Fall River, St. Luke's Hospital in New Bedford, and Tobey Hospital in Wareham, Massachusetts.

17. Steward St. Anne's owns and operates St. Anne's. St. Anne's is located less than two miles from Charlton Memorial Hospital and less than fifteen miles from St. Luke's Hospital. Steward St. Anne's parent corporation, Steward Health Care, owns numerous other hospitals in the Commonwealth.

Overview of the Relevant
Statutory and Regulatory Scheme

18. M.G.L. c. 111, § 51, authorizes DPH to license for two years persons it "deems responsible and suitable to establish or maintain a hospital." The statute provides further that "[n]o original license shall be issued to establish or maintain a hospital . . . unless there is a determination by the department that there is a need for such facility at the designated location."

19. DPH's regulations promulgated pursuant to, among other statutes, M.G.L. c. 111, § 51, set forth standards for the maintenance and operation of hospitals. *See* 105 CMR 130.000, *et seq.* (the "Regulation"). The Regulation, which is entitled "Hospital Licensure," "applies to every hospital subject to licensure under M.G.L. c. 111, §§ 51 through 56," except as otherwise stated in the regulation. *See* 105 CMR 130.003 and 130.010.

20. Pursuant to the Regulation, each license must list, among other things, "the specific service(s) which the hospital is licensed to deliver." 105 CMR 120.120. "Service" is defined to include, among numerous other things, "Cardiac Catheterization Services." 105 CMR 130.020(U). If the hospital meets the relevant requirements, DPH "shall cause the license issued to a hospital pursuant to 105 CMR 130.120 to indicate that the licensee is authorized to provide cardiac catheterization services as a specific service of the hospital." 105 CMR 130.915(A). To the extent a licensed hospital wishes to provide cardiac catheterization services, it may apply for an amended hospital license adding such service. *See* 105 C.M.R130.926 ("Upon approval of the application to provide cardiac catheterization services, the Department shall issue an amended hospital license which indicates that cardiac catheterization is an approved service provided by the hospital.").

21. The Regulation does not provide for DPH to issue separate licenses to perform individual services. Instead, the Regulation provides that DPH will issue a single license identifying all of the services to be provided.

22. In addition to licensure requirements, any hospital wishing to make substantial capital expenditures for the construction of a health care facility or substantially change the service of the facility must obtain a Determination of Need ("DoN") from DPH. M.G.L. c. 111, § 25(C).

23. According to DPH's website, the Massachusetts Legislature established the Determination of Need ("DoN") program in 1971 to:

> encourage equitable geographic and socioeconomic access to health care services, help maintain standards of quality, and constrain overall health care costs by eliminating duplication of expensive technologies and services. DoN receives applications from health care facilities planning substantial capital expenditures or substantial change in services. It is the responsibility of DoN to evaluate proposals and make recommendations to the Public Health Council for approval or denial of the expenditures and/or new services.

(Emphasis added.)

24. DPH's Determination of Need Regulations (the "Regulations"), 105 CMR 100.001, provide, in pertinent part,

> The objective of the determination of need process shall be the allocation of health care resources and the improvement of health care delivery systems such that adequate health care services are made reasonably available to every person within Massachusetts at the lowest reasonable aggregate cost and to ensure the non-duplication of services.

(Emphasis added.)

25. While a DoN is not required to provide cardiac catheterization services, no hospital may offer such services without DPH's prior approval. *See* 105 CMR 130.900 and 130.915(A).

26. The regulatory scheme established by the Legislature in G.L. c. 111, and by DPH in regulations it has promulgated, is designed, in part, to ensure delivery of quality patient care and to control costs by avoiding the duplication of services and expensive technology in a particular geographic area. Avoiding duplication of services in an area ensures sufficient patient volume for physicians to gain and maintain expertise in providing cardiac catheterization services. The scheme thus prevents wasteful competition that would be counterproductive to health care quality.

The Moratorium Circular

27. In May 2008, after receiving extensive review and input from, among others, the Massachusetts Chapter of the American Heart Association, the Massachusetts Hospital Association, the Massachusetts College of Emergency Physicians, the Massachusetts Medical Society, and DPH's Invasive Cardiac Services Advisory Committee, DPH issued Circular Letter CHCQ 08-05-486 in which it announced

> The Department [of Public Health] will *monitor the existing system for the impact and effectiveness* of the cardiac point-of-entry plans. *To that end*, effective immediately, the Department will not accept an application for approval of a new cardiac catheterization service if the hospital is located within 30 minutes travel time (via emergency ambulance) of a hospital that currently provides primary angioplasty 24 hours/day, seven days/week.

(Emphasis added.) A true and accurate copy of that circular is attached hereto as *Exhibit 1* (the "Moratorium Circular").

28. The rationale for the Moratorium Circular was to allow physicians to gain and maintain expertise in performing cardiac catheterization procedures by limiting the number of competing programs, thus ensuring their ability to provide quality patient care. DPH has long considered volume in cardiac catheterization procedures to be a surrogate for quality in performance of such procedures. *See* Memorandum attached hereto as *Exhibit 2*, at 1. For this

reason, DPH regulations require hospitals performing cardiac catheterization procedures to meet minimum volume requirements. *See* 105 CMR 130.935(A) and (B).

29. Because Southcoast's Charlton Memorial is located within two miles from St. Anne's, and thus within 30 minutes' travel time via emergency ambulance, and because Charlton Memorial offers cardiac catheterization services, including 24-hour primary angioplasty services, seven days a week, the Moratorium Circular bars DPH from accepting an application from Steward St. Anne's for approval of a new cardiac catheterization service at St. Anne's.

Steward St. Anne's Applies for a DoN

30. In 2012, Steward St. Anne's sought approval from the DoN Program to construct a new three-story wing at St. Anne's. Part of the proposed project involved construction of 11,476 square feet of "shell space," the purpose of which Steward did not disclose at the time it filed its request. The Public Health Council, the DPH body that reviews and makes final agency determinations on DoN requests, approved the requested DoN (DoN #5-3CO8) subject to the requirement that Steward St. Anne's submit a "Request for Significant Change Amendment" ("Significant Change Amendment") before devoting the shell space to clinical uses.

31. In August 2013, Steward St. Anne's requested a Significant Change Amendment, declaring its intention to establish a new cardiac catheterization service in the previously denominated "shell space." A true and accurate copy of this Request is attached hereto as *Exhibit 3*.

32. Southcoast opposed Steward St. Anne's request for a Significant Change Amendment on the grounds that, among other things, there was no established need for additional cardiac catheterization services in the Fall River/New Bedford area, and thus the St. Anne's cardiac catheterization service would duplicate Southcoast's service.

33. In October 2013, DoN Director, Bernard Plovnik, advised Steward St. Anne's that the DoN program could not approve the Significant Change Amendment because under the Moratorium Circular, it was "clear that the finished project cannot be licensed for the service that is proposed. Likewise, [Steward St. Anne's] should understand that the submission of a DoN request cannot be used to circumvent clear guidance on a moratorium for the license of a particular service." A true and accurate copy of the letter from Mr. Plovnik is attached hereto as *Exhibit 4*.

The ACO Exception Circular

34. According to DPH, Massachusetts diagnostic catheterization volume declined 27% from 2005 to 2012.

35. Nevertheless, in early 2014, following Director Plovnik's response to Steward St. Anne's, then-Secretary of EOHHS, John Polanowicz—a Steward Health Care executive before he became Secretary who returned to Steward Health Care after leaving his position as Secretary—took steps to allow Steward St. Anne's to circumvent the Moratorium Circular to provide a cardiac catheterization service at St. Anne's. Not later than August 2014, and perhaps earlier, Steward Health Care began speaking with Secretary Polanowicz about returning to Steward Health Care in a senior executive position after his tenure as Secretary ended.

36. At Secretary Polanowicz's direction, DPH began drafting a new cardiac catheterization "policy." After DPH had been working on the policy for a period of time, the Secretary reminded the Commissioner of DPH as follows: "I am trying to accomplish . . . [among other things, so]. . . an A[ccountable] C[are] O[rganization] (HPC or Pioneer hospital-based) can transfer from one site not meeting the requirements to the other site, if that location is

closed to catheterization (peripherals could still be done)." A true and accurate copy of this email is attached hereto as *Exhibit 5*.

37. Internal DPH emails and drafts of the ACO Exception Circular reveal that DPH developed the new policy for the benefit of Steward Health Care hospitals, including Steward St. Anne's. *See* cover email from Nancy Murphy dated March 19, 2014, asking whether the language might "open the door" for certain non-Steward Health Care hospitals, and the last paragraph of the draft policies attached thereto titled "Questions," attached as *Exhibit 6.*

38. Internal DPH emails also indicate that representatives of Steward Health Care provided comments on multiple drafts of the policy and repeatedly requested information on its status, as follows:

A. In an email dated May 5, 2014, from Jill Judd, upon information and belief, then-Executive Assistant to Secretary Polanowicz, to then-DPH Commissioner Cheryl Bartlett, Ms. Judd wrote: "Hi Commissioner! Steward is asking for an update on cath labs, should I check in w/secretary on this? I know you discussed at your 1:1 last week, not sure if you have the next steps." A true and accurate copy of this email is attached hereto as *Exhibit 7.*

B. In an email dated May 21, 2014, Nancy Murphy of DPH reminded Associate Commissioner Biondolillo that St. Anne's used to have a cardiac catheterization service, but closed because it did not have any volume. Associate Commissioner Biondolillo said she thought she remembered "Andy," Steward Health Care's outside counsel, telling her that St. Anne's had formerly had a cardiac catheterization service. A true and accurate copy of this email is attached hereto as *Exhibit 8.*

C. Upon information and belief, Secretary Polanowicz met with Steward representatives on June 10 regarding the cardiac "cath lab" issue. *See* May 27 email from Jill

Judd ("[t]hey [Steward] will be here on June 10 for a masshealth [sic] meeting. They're very eager to hear back from us on this, I'll see if they can stick around for a little bit afterwards."). A true and accurate copy of Ms. Judd's email is attached hereto as *Exhibit 9*.

D. By email dated June 11, 2014, Director Allwes wrote to Commissioner Bartlett and Associate Commissioner Biondolillo, "You will notice I did not incorporate [in the attached draft of the cardiac cath moratorium] suggestions from Steward Healthcare. While their suggested edits were thoughtfully considered, I did not think they represented the launguage [sic] that DPH would want this to include." A true and accurate copy of this email is attached hereto as *Exhibit 10*.

E. In an email dated June 18, 2014, from Deborah Allwes, Director of Bureau of Health Care Safety and Quality, to Madeleine Biondolillo, Associate Commissioner of DPH, a true and accurate copy of which is attached hereto as *Exhibit 11*, Ms. Allwes wrote:

> Madeleine, attached is the most recent version of the moratorium. It is the one the secretary sent me (below). It does not have the rationales for why these changes are proposed. I was not involved in any discussions leading to the changes on the moratorium so am not sure what the exact rationales are.
>
> I will send you Stewart's [sic] recommended additions in a subsequent email. I do not propose including their recommended changes (they want to add a number 7 and 8 to the moratorium).

39. After the repeated communications between Steward Health Care and DPH, in July 2014, the DPH issued ACO Exception Circular, DHCQ 14-6-617. A true and accurate copy of the ACO Exception Circular is attached hereto as *Exhibit 12*.

40. DPH did not hold a public hearing or provide notice to interested parties before issuing the ACO Exception Circular, nor did it give any opportunity for affected parties to present arguments against the ACO Exception Circular.

41. DPH also did not afford the Public Health Council the opportunity to deliberate on the merits of the policy changes reflected in the ACO Exception Circular, thus arrogating to itself the Public Health Council's statutory role as the arbiter and issuer of licensure regulations. *See* G.L. c. 111, § 3.

42. The ACO Exception Circular provides, in relevant part,

> The moratorium on establishment of a new cardiac catheterization service within 30 minutes of an existing percutaneous coronary intervention (PCI)-capable hospital remains in effect, except under the following limited circumstances.
>
> 1. A hospital that proposes a new cardiac catheterization service within the geographic limitation set by the moratorium is part of a health care system recognized as a Pioneer ACO, a Medicare Shared Savings Plan ACO, or other ACO designation to be determined by the Department; the hospital system has an existing cardiac catheterization service at another hospital within its system that does not meet the minimum diagnostic volume (300 procedures); and the hospital system is proposing to transfer the existing service license to establish a new diagnostic cardiac catheterization service at another hospital in the same ACO system.
>
> 2. The ACO will document, to the Department's satisfaction, the projected volume of diagnostic cardiac catheterization procedures at the proposed new site and the underlying assumptions associated with the volume projection, including:
>
>   a. Where the patient population the ACO assumes it would treat at the new site is currently receiving diagnostic cardiac catheterization procedures; and
>   b. How the ACO anticipates ensuring these patients will use the service at the new diagnostic cardiac catheterization site.
>
> An eligible ACO should submit to the Department a letter of intent to transfer the location of a cardiac catheterization service from one hospital license to another within its ACO. The letter shall describe which hospital will close its cardiac catheterization service and which will open a proposed new cardiac catheterization service. The letter will include the information described in #2, above.

Thus, the ACO Exception Circular permits a facility that satisfies its requirements to perform diagnostic cardiac catheterizations.

43. The ACO Exception Circular is inconsistent with DPH's existing licensure regulations in multiple respects including, but not limited to, the following:

A. The licensure regulations do not contemplate or authorize transferable separate "service licenses."

B. The licensure regulations do not contemplate or authorize the transfer of a cardiac catheterization service between hospitals based on the hospitals' enrollment in a common ACO.

C. Under 105 C.M.R. §§ 130.940, 130.950, and 130.955, an applicant is subject to detailed staffing, equipment, and supportive diagnostic service requirements, and DPH is required to conduct "an inspection or other investigation" to determine compliance with them. The ACO Exception Circular is silent in all these regards.

D. Under 105 CMR 130.920, applicants are required to "list the specific procedures that are proposed to be provided by the cardiac catheterization service." The ACO Exception Circular does not require such a list.

E. Under 105 CMR 130.920, a hospital that wishes to provide cardiac catheterization services must document how it will satisfy the detailed minimum workload requirements set forth in 105 CMR 130.935. Under the ACO Exception Circular, a hospital need only state "the projected volume of diagnostic cardiac catheterization procedures at the proposed new site and the underlying assumptions associated with the volume projection."

F. Under 105 CMR 130.924(A), DPH is required to conduct "an inspection or other investigation of the facility" and has determined that the applicant complies with the regulations applicable to cardiac catheterization services. The ACO Exception Circular calls only for an "architectural plan review process for the new cardiac catheterization service."

G. Under 105 CMR 130.920, a hospital that wishes to provide cardiac catheterization services must submit a notarized application to DPH signed under the pains and penalties of perjury. Under the ACO Exception Circular, a hospital can request to open a cardiac catheterization service by submitting only a "Letter of Intent."

44. Steward operates an ACO. While the ACO Exception Circular, on its face, applies to all ACOs, it was developed with the specific intention of benefiting Steward Health Care hospitals, including Steward St. Anne's. *See* Ex. 6, Questions in draft policy.

45. Steward quickly availed itself of the ACO Exception Circular. In August 2014, Steward submitted a Notice of Intent to transfer its Cardiac Catheterization Service from QMC to St. Anne's. A true and accurate copy of this Notice of Intent is attached hereto as *Exhibit 13* (the "Notice of Intent").

46. In response to the Notice of Intent to Transfer, Southcoast submitted a letter to Mr. Plovnick arguing that allowing Steward Health Care to transfer a cardiac catheterization service license to St. Anne's would result in fragmentation and reduced quality of patient care, and create an unlawful bypass of DoN and licensing requirements. A true and accurate copy of this response is attached hereto as *Exhibit 14*. Southcoast also asserted that Steward Health Care's Notice of Intent failed to satisfy the standards of the ACO Exception Circular, and would result in reduced quality of patient care. *Id.*

47. The DPH neither approved nor disapproved the Notice of Intent in 2014.

48. Upon information and belief, no other hospital in the Commonwealth submitted a Notice of Intent to Transfer pursuant to the ACO Exception Circular.

Steward's Significant Change Amendment

49. On December 10, 2014, the Public Health Council met to consider St. Anne's Request for Significant Change Amendment to the DoN previously granted to Steward St. Anne's for the construction of shell space.

50. At that meeting, Southcoast called attention to the recommendations of the Invasive Cardiac Services Advisory Committee, and noted that the ACO Exception Circular materially changed DPH regulations regarding the licensing of cardiac catheterization services, yet was implemented with no notice, no public hearing, and no consideration by the Council

(which has the sole authority to approve all regulatory changes), such that the ACO Exception Circular violated G.L. c. 30A and thus was of no legal effect.

51. The Council questioned DPH staff about the reasons behind the issuance of the ACO Exception Circular, and whether a new cardiac catheterization service at St. Anne's would result in duplication of services. At the conclusion of the meeting, the Council voted to table the Significant Change Amendment request "pending further information from health planning, further clarification regarding the [ACO Exception Circular], and an assessment of the potential impact on public health based upon projections in [the Fall River/New Bedford] area." It asked staff to return to the Council with additional information in not more than six months. A true and accurate copy of the minutes of the Council's December 10 meeting are attached hereto as *Exhibit 15*. DPH staff did not do this.

Closure of Quincy Medical Center

52. When it purchased QMC in 2011, Steward Health Care committed to the Attorney General of the Commonwealth that it would not close that facility for at least 6.5 years. *See* Statement of the Attorney General as to the Quincy Medical Center Transaction dated September 7, 2011, a true and accurate copy of which is attached hereto as *Exhibit 16*, at 4, ¶(d).

53. Nevertheless, Steward Health Care decided in 2014 to close QMC.

54. Before it closed, QMC was licensed to provide, among other services, cardiac catheterization services.

55. Clearly concerned that the closing of QMC would leave Steward without a "cardiac catheterization license" to transfer to St. Anne's, on December 11, 2014, Steward Health Care's outside counsel, Andrew Levine, repeatedly attempted to obtain "confirmation from DPH that the transfer of the QMC cardiac catheterization service to St. Anne's was

effective subject to location only and without regard to the proposed closure of QMC." A true and accurate copy of Mr. Levine's letter dated December 11, 2014, is attached hereto as *Exhibit 17*. True and accurate copies of his follow-up emails to DPH staff on December 23, 26, and 29, 2014, are attached hereto as *Exhibit 18*.

56. DPH's Deborah Allwes, Director of the DPH Bureau of Healthcare Safety and Quality ("HCSQ"), responded to Mr. Levine that she needed to take the matter up with legal, and would get back to him. *Id.*

57. On December 26, 2014, QMC ceased all business operations.

58. On December 30, 2014, Steward Health Care, through Mr. Levine, submitted the requisite Facility Closure Form for QMC, and surrendered QMC's hospital license to DPH. In a letter accompanying these forms, Mr. Levine wrote: "Accordingly, the [QMC] has completed the closure process. Former patients of the Hospital may contact Steward Carney Hospital, Inc. in Dorchester, MA regarding their prior medical records." A true and accurate copy of Mr. Levine's letter with the Facility Closure Form and QMC's hospital license are attached hereto as *Exhibit 19*.

59. Even though QMC had closed, Mr. Levine reiterated in the cover letter Steward Health Care's request that QMC's license to operate a cardiac catheterization service be "preserved," for an eventual relocation of the service to St. Anne's. *Id.*

60. Upon information and belief, DPH has never confirmed that QMC's license was preserved. Upon information and belief, DPH never made such confirmation because it knew that neither the licensure statute, the Regulations, nor the ACO Exception Circular permitted the transfer of any part or all of a hospital license and, in particular, the transfer of a cardiac

catheterization service from a hospital that was no longer licensed to provide that service or any other services to another hospital in the closed hospital's system.

61. The hospital license QMC surrendered in December 2014 was scheduled, by its terms, to expire on September 30, 2015. *See* attachment 2 to Ex. 19. Thus, even if the license were somehow preserved following QMC's closure, it has expired.

DPH Suspends the ACO Exception Circular, and
Then Vacates the Suspension

62. In January 2015, DPH issued a memorandum suspending the entirety of the ACO Exception Circular, including the new license transfer process for ACOs (the "Suspension Circular"). A true and accurate copy of the Suspension Circular is attached hereto as *Exhibit 20.*

63. In the Suspension Circular, DPH stated, among other things:

> The Department has suspended the July Circular Letter [i.e., the ACO Exception Circular] to allow the Department to re-evaluate the July Circular Letter guidance in the context of best practices, national guidelines, patient outcomes, safety and quality for cardiac catheterization. The Department expects to conduct its review during the next four to six months. At the conclusion of the Department's review, the Department plans to bring recommendations to the Public Health Council for input and guidance.

64. By letter dated April 2, 2015, the DoN Program requested information from Southcoast and Steward St. Anne's in response to questions posed by the Council at the Council's December 2014 meeting. A true and accurate copy of that request for information is attached hereto as *Exhibit 21.*

65. Southcoast responded to the request for information. A true and accurate copy of this response is attached as *Exhibit 22.* Even though Steward St. Anne opined that "[t]he information requested by the Department is very concerning and inappropriate for several reasons," it, too, responded to the request. *See,* a true and accurate copy of Steward St. Anne's response, at Exhibit 23 at 3, *et seq.*

66. On April 28, 2015, without providing the Council with the information the Council had requested at the December 10, 2014, meeting, and without bringing recommendations to the Council as indicated in the Suspension Circular, DPH issued a circular revoking the Suspension Memorandum "effective immediately." In that circular, DPH stated that it "is currently reviewing best practices, national guidelines, patient outcomes, safety and quality for cardiac catheterization. The Department expects this review to be completed by May, 2015." A true and accurate copy of this circular is attached hereto as *Exhibit 24* (the "Revocation of Suspension Circular").

67. Steward Health Care takes the position that the effect of the Revocation of Suspension Circular was to again give it the opportunity to transfer cardiac catheterization services from QMC to St. Anne's pursuant to the ACO Exception Circular.

The Council Defers Action on Significant Change Amendment and Acknowledges the "ACO Loophole"

68. At the May 2015 Public Health Council meeting, Director Allwes presented a report concluding that the existing cardiac catheterization licensing regulations needed to be updated. She commented that ICSAC had concluded that no new percutaneous coronary intervention ("PCI") programs were needed in the Commonwealth.

69. Council members supported the need for new regulations and suggested that the approval of Steward's Significant Change Amendment should not move forward until new regulations were issued.

70. At the meeting, Dr. Woodward, a member of the Council, expressed concern about establishing another cardiac catheterization lab so close to Southcoast's. A true and accurate copy of the Minutes of the Public Health Council meeting on May 10, 2015, is attached

hereto as *Exhibit 25*, at 6. Another Public Health Council member, Dr. Rosenthal, noted that the "ACO loophole that was announced last [July] concerns me as it allows the entity to circumvent the [DoN] process." *Id.* When Dr. Woodward asked about the timing of the Steward DoN the Council had reviewed, DPH staff responded that it was "under review." *Id.*

Steward St. Anne's Withdrawal of its
Significant Change Amendment

71. Steward St. Anne's thereafter decided to house the proposed cardiac catheterization service in an existing space within St. Anne's rather than in the "shell space." This decision meant that Steward St. Anne's would no longer need to pursue approval of its DoN Significant Change Amendment from the Council.

72. By letter dated August 28, 2015, Steward Health Care's counsel, Andrew Levine advised DPH that Steward Health Care was withdrawing its request for a Significant Change Amendment. A true and accurate copy of this letter is attached hereto as *Exhibit 26*.

73. Upon information and belief, after withdrawing the Significant Change Amendment, Steward Health Care requested approval from DPH to transfer cardiac catheterization services from QMC to St. Anne's pursuant to the ACO Exception Circular.

74. Upon information and belief, the process for Steward St. Anne's to open a cardiac catheterization service at St. Anne's pursuant to the ACO Exception Circular is moving forward on an expedited basis.

75. Upon information and belief, DPH approval for St. Anne's to open a cardiac catheterization service at St. Anne's is imminent.

76. Upon information and belief, Steward St. Anne's has not commenced providing cardiac catheterization services at St. Anne's.

77. From the outset of its attempt to provide cardiac catheterization services at St. Anne's, Steward St. Anne's has been unable to demonstrate a need for such services in the area given that Southcoast is providing them, the demand for them at St. Luke's is barely above the minimum mandated by DPH, and Charlton is operating below capacity.

Irreparable Harm to Southcoast of Steward
St. Anne's Opening A Cardiac Catheterization Unit

78. The number of diagnostic cardiac catheterization procedures performed at St. Luke's has declined annually from 656 in 2011 to 440 in 2014. If the frequency of such procedures thus far in 2015 continues for the remainder of the year, St. Luke's will perform only 387 procedures in 2015. Because 45% of the procedures in 2014 at St. Luke's were performed by Steward Health Care physicians, and Steward Health Care physicians would almost certainly perform their diagnostic cardiac catheterization procedures at St. Anne's if DPH so authorized, there is a strong likelihood that would cause the number of diagnostic procedures performed at St. Luke's to fall below the minimum 300 annual procedure threshold, putting the cardiac catheterization services at St. Luke's at risk of closure.

79. In calendar year 2014, Southcoast's Charlton Hospital performed 1,766 diagnostic cardiac catheterization procedures. Of these, 634 were performed by physicians employed by hospitals in Steward Health Care's ACO. At St. Luke's Hospital, 440 diagnostic cardiac catheterization procedures were performed. Of these, 199 were performed by physicians employed by hospitals in Steward Health Care's ACO. Accordingly, if Steward St. Anne's were able to perform cardiac catheterization services, Steward Health Care physicians would presumably perform them at Steward St. Anne's, thus causing Southcoast to lose revenue that it will never be able to recover even if it obtains the declaratory relief requested in this action.

The Balance of Harms Favors
Entry of an Injunction

80. As noted above, there is substantial risk that Southcoast will suffer irreparable harm if DPH were to authorize Steward St. Anne's to provide cardiac catheterization services at St. Anne's before Southcoast's requests for declaratory relief are resolved.

81. There would be no harm to DPH if it were enjoined from authorizing Steward St. Anne's to provide cardiac catheterization services at St. Anne's before Southcoast's requests for declaratory relief are resolved, as the injunction would simply maintain the status quo.

82. There would be no harm to Steward St. Anne's if it were enjoined from providing cardiac catheterization services at St. Anne's before Southcoast's requests for declaratory relief are resolved, as the injunction would simply maintain the status quo.

Harm to the Public Interest of Steward
St. Anne's Opening A Cardiac Catheterization Unit

83. Permitting St. Anne's to perform diagnostic cardiac catheterization procedures would also adversely affect the public interest in at least four ways.

A. First, based on Southcoast's experience, approximately 30% of all patients who received a diagnostic cardiac catheterization procedure required an interventional procedure, including the potential for open heart surgery. If cardiac catheterization procedures were permitted at St. Anne's, it would be reasonable to project that approximately 30% of the patients who received diagnostic cardiac catheterization there would need to be transferred to another facility for an interventional procedure. This would result in additional costs in connection with the transfer of patients, not to mention significant inconvenience and heightened risk to patients.

B. Second, physician peers and surgical consultants who are qualified to review therapeutic options are not likely to be present in a low-volume setting with no advanced cardiac services. As a result, patients are less likely to receive the benefit of the "real time" discussion and consultation between physicians that occurs naturally in comprehensive cardiac programs.

C. Third, transporting patients with arterial access sutured in place from the diagnostic procedures to another facility for PCI puts the patients at risk of bleeding and local complications at the arterial access site. Removing the arterial access and performing another puncture at another location exposes patients to unnecessary risk.

D. Fourth, at St. Luke's, 84% of the catheterization lab patients are Medicare (primarily elderly) or Medicaid (lower income) patients. These elderly and low-income patients rely heavily on public transportation. The closure of St. Luke's service would cause additional hardships for this vulnerable population for whom transportation to Fall River is not only an inconvenience, but also an additional financial burden.

84. Further, 42% of the St. Luke's patients are low income, i.e., residing in zip codes with median incomes below 200% of the federal poverty level. St. Anne's admits that it intends to transfer patients who require interventional cardiac services to other hospitals within the Steward Health Care system. See Ex. at 10, B3. The Steward Health Care hospital that performs interventional cardiac services that is closest to St. Anne's is Good Samaritan, in Brockton, 34 miles from St. Anne's. Requiring cardiac patients to travel 34 miles for interventional cardiac services will, upon information and belief, be detrimental to their health and inconvenient for their families, families who, as noted above, are heavily dependent on public transportation.

COUNT I
(Declaratory Judgment)

85. Southcoast realleges and incorporates by reference the allegations of the preceding paragraphs.

86. The Administrative Procedure Act states that "a public hearing is required prior to the adoption, amendment or repeal of any regulation if . . . a public hearing is required by the enabling legislation of the agency or by any other law, or a public hearing is required as a matter of constitutional right." M.G.L. c. 30A, § 2.

87. Even if a public hearing is not required by section 2, the agency must "give notice and afford interested persons an opportunity to present data, views or arguments" at least 21 days before the proposed action. M.G.L. c. 30A, § 3.

88. The ACO Exception Circular makes non-interpretative, substantive amendments to the Cardiac Catheterization Licensing regulations promulgated by DPH and codified at 105 CMR 130.900, *et seq.*, in that it permits the transfer of a license to operate a cardiac catheterization service from one hospital to another, does so based on participation in an ACO, and does not require the hospital that will be receiving the license to satisfy the licensing requirements of 105 C.M.R. 130.915, *et seq.*

89. Because the ACO Exception Circular makes material and substantive changes to the Regulations, and it was not promulgated pursuant to the notice and comment provisions of the Administrative Procedures Act, it is of no force and effect.

90. Because the ACO Exception Circular makes material and substantive changes to the Regulations, and the Public Health Council did not approve it as required by M.G.L. c. 111, § 3, it is of no force and effect.

91. There is an actual controversy as to whether the ACO Exception Circular violates the APA and/or M.G.L. c. 111, § 3, and thus whether it is enforceable in accordance with its terms.

92. Entry of a declaratory judgment will end the controversy as to whether the ACO Exception Circular is enforceable in accordance with its terms.

WHEREFORE, Southcoast respectfully requests the relief set forth below:

COUNT II
(Declaratory Relief)

93. Southcoast realleges and incorporates by reference the allegations of the preceding paragraphs.

94. Steward Health Care proposes to transfer what had been a license to provide cardiac catheterization procedures at QMC to Steward St. Anne's pursuant to the ACO Exception Circular and Steward St. Anne's Notice of Intent.

95. Steward Health Care chose to close QMC permanently in December 2014.

96. QMC returned its hospital license, including the notation thereon of its ability to operate cardiac catheterization services, to DPH in or about December 2014.

97. On September 30, 2015, the license to operate a hospital that QMC had held expired by its terms, if not earlier.

98. The ACO Exception Circular authorizes the transfer of a license where the ACO hospital system "has an *existing* cardiac catheterization service at another hospital within its system that does not meet the minimum diagnostic volume (300) procedures; and the hospital system is proposing to transfer the *existing* service license to establish a new diagnostic cardiac catheterization service at another hospital in the ACO system." (Emphases added.)

99. Without a valid existing license to transfer, Steward Health Care cannot satisfy the requirements of the ACO Exception Circular to be able to provide cardiac catheterization services at St. Anne's.

100. There is an actual controversy as to whether Steward Health Care may transfer what had been the QMC license to Steward St. Anne's pursuant to the ACO Exception Circular to enable St. Anne's to operate a cardiac catheterization service.

101. Entry of a declaratory judgment will end the controversy as to whether Steward Health Care may transfer what had been the QMC license to Steward St. Anne's pursuant to the ACO Exception Circular to enable St. Anne's to operate a cardiac catheterization service.

WHEREFORE, Southcoast requests the relief set forth below:

COUNT III
(To Compel DPH to Produce Withheld Documents Responsive to Southcoast's Public Records Request)

102. Southcoast realleges and incorporates by reference the allegations of the preceding paragraphs.

103. On November 26, 2014, Southcoast sent a public records request, pursuant to G.L. c. 66, § 10, to DPH. A true and accurate copy of a letter to DPH dated June 17, 2015, following up on that request is attached hereto as *Exhibit 27*.

104. In that Request, Southcoast requested the following documents:

> All communications including letters, applications, recordings, transcripts, memoranda, and documents of any kind whatsoever by and/or between the Massachusetts Department of Public Health, including the Public Health Council, and any of it employees, lawyers, or other agents, and Steward Health Care System, and any of its employees, lawyers, or other agents, regarding:
>
> 1. Steward St. Anne Hospital Corporation Determination of Need Project #5-3C08;
>
> 2. Steward's Request for Significant Change Amendment to DoN #4-3C08;
>
> 3. Steward's Intent to Transfer Quincy Medical Center's cardiac catheterization license to St. Anne's Hospital;
>
> 4. Circular Letter DHCQ14-6-617 regarding policy updates for cardiac catheterization services; and
>
> 5. The decision to close the Quincy Medical Center.

Id.

105. While DPH has produced some documents responsive to the Request, by letter dated August 12, 2015, DPH advised Southcoast that it was "continu[ing] to assert the deliberative process exemption to the public records law, M.G.L. c. 4, § 7(d), to emails regarding [Steward St. Anne's Corporation's Significant Change Amendment to Determination of Need Project #5-3C08] that are dated January 2015 to the present. We assert that these emails remain exempt from disclosure because the Department has not made a decision on this application." A true and accurate copy of this letter is attached hereto as *Exhibit 28*.

106. In connection with that letter, DPH delivered a "privilege log" to Southcoast. *See Exhibit 29*.

107. Although Steward St. Anne's withdrew the Significant Change Amendment request in August 2015, thus terminating any need for DPH to make a decision on the application, DPH has not produced the documents it withheld on the basis of the deliberative process exemption.

108. In addition, although DPH acknowledged in internal emails that it had received comments on the draft ACO Exception Circular from Steward Health Care's counsel, Mr. Levine (*see* Exs. F, I, and J), DPH has failed to produce documents concerning or evidencing Mr. Levine's comments.

109. DPH should be compelled to produce all documents responsive to the Public Records Request within ten (10) days after entry of an Order compelling it to do so because Southcoast is entitled to the documents under M.G.L. c. 66, § 10(b) and the public records access regulations at 950 C.M.R. 32.00, *et seq.*

WHEREFORE, Southcoast requests the relief set forth below.

REQUESTS FOR RELIEF

Southcoast respectfully requests that this Court:

A. Enter judgment in its favor on Count I against DPH declaring that the ACO Exception Circular is unenforceable because it was issued in violation of the Administrative Procedure Act and/or M.G.L. c. 111, § 3.

B. Enter judgment in its favor on Count II against Steward Health Care declaring that even if the ACO Exception Circular is enforceable in accordance with its terms, Steward Health Care cannot satisfy the requirements of the ACO Exception Circular so as to enable it to transfer cardiac catheterization services that had been performed at QMC to Steward St. Anne's.

C. Enter judgment in its favor on Count III against DPH requiring DPH to produce all documents responsive to Southcoast's public records request within ten days after entry of such order.

D. On Counts I-II, after notice and a hearing, entry of an order preliminarily enjoining defendants Massachusetts Department of Public Health and Monica Bharel, M.D., in her capacity as Commissioner of the Massachusetts Department of Public Health, from authorizing or approving a cardiac catheterization service for Steward St. Anne's Hospital Corporation to provide at St. Anne's Hospital;

E. On Counts I-II, after notice and a hearing, entry of an order preliminarily enjoining defendant Steward St. Anne's Hospital Corporation from providing cardiac catheterization services at St. Anne's Hospital; and

F. On all Counts, granting Southcoast such other relief as may be appropriate and just.

Respectfully submitted,

Dated: October 15, 2015

SOUTHCOAST HEALTH SYSTEMS, INC.,

By its attorneys,

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VERIFICATION

I, Linda Bodenmann, am the Chief Operating Officer of plaintiff Southcoast Health Systems, Inc. ("Systems"). I have been employed in this capacity since July 2011. Prior to that time, I served as COO of the plaintiff, Southcoast Hospitals Group, Inc. As COO of Systems, I am responsible for Southcoast Hospitals Group operations, and the operations of certain related entities.

I have read the foregoing Verified Complaint. Except as to matters stated to be on information and belief, the facts set forth above are true and correct to the best of my knowledge and belief based on my personal knowledge, information provided to me by others employed or otherwise engaged by Southcoast, and the books and records of Southcoast. As to those facts stated to be on information and belief, I believe them to be true.

Signed under the pains and penalties, the 15th day of October, 2015.

Linda Bodenmann

Linda Bodenmann, COO