STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION

STATE OF FLORIDA, AGENCY FOR
HEALTH CARE ADMINISTRATION,

Petitioner,

v.

AHCA No. 2018007502
Facility Type: Hospital

FLORIDA HEALTH SCIENCES
SERVICES INC. d//b/a
TAMPA GENERAL HOSPITAL,

Respondent.
_____/

FINAL ORDER

Having reviewed the Administrative Complaint, and all other matters of record, the Agency for Health Care Administration finds and concludes as follows:

1. The Agency issued the attached Administrative Complaint and Election of Rights form to the Respondent. (Ex. 1). The Election of Rights form advised of the right to an administrative hearing. The Respondent returned the Election of Rights form selecting "Option 1" (Ex. 2), thus waiving the right to a hearing to contest the allegations and sanction sought in the Administrative Complaint.

Based upon the foregoing, it is **ORDERED:**

2. The findings of fact and conclusions of law set forth in the Administrative Complaint are adopted and incorporated by reference into this Final Order.

3. The Respondent shall pay the Agency $12,800.00. If full payment has been made, the cancelled check acts as receipt of payment and no further payment is required. If full payment has not been made, payment is due within 30 days of the Final Order. Overdue amounts are subject to statutory interest and may be referred to collections. A check made payable to the "Agency for Health Care Administration" and containing the AHCA ten-digit case number should be sent to:

Central Intake Unit
Agency for Health Care Administration
2727 Mahan Drive, Mail Stop 61
Tallahassee, Florida 32308

ORDERED at Tallahassee, Florida, on this 13 day of November, 2018.

Justin M. Senior, Secretary
Agency for Health Care Administration

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review, which shall be instituted by filing one copy of a notice of appeal with the Agency Clerk of AHCA, and a second copy, along with filing fee as prescribed by law, with the District Court of Appeal in the appellate district where the Agency maintains its headquarters or where a party resides. Review of proceedings shall be conducted in accordance with the Florida appellate rules. The Notice of Appeal must be filed within 30 days of rendition of the order to be reviewed.

CERTIFICATE OF SERVICE

I CERTIFY that a true and correct copy of this Final Order was served on the below-named persons by the method designated on this 13th day of November, 2018.

Richard J. Shoop, Agency Clerk
Agency for Health Care Administration
2727 Mahan Drive, Mail Stop 3
Tallahassee, Florida 32308
Telephone: (850) 412-3630

Facilities Intake Unit Agency for Health Care Administration (Electronic Mail)	Central Intake Unit Agency for Health Care Administration (Electronic Mail)
Thomas J. Walsh II, Senior Attorney Office of the General Counsel Agency for Health Care Administration (Electronic Mail)	Denise Jones Director of Risk Management One Tampa General Circle Tampa, Florida 33606 (U.S. Mail)

STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION

STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION,

Petitioner,

vs.

Case Nos. 2018007502
Facility Type: Hospital

FLORIDA HEALTH SCIENCES CENTER, INC. d/b/a TAMPA GENERAL HOSPITAL,

Respondent.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW the Agency For Health Care Administration (hereinafter Agency), by and through the undersigned counsel, and files this Administrative Complaint against Florida Health Sciences Services, Inc. d/b/a Tampa General Hospital (hereinafter Respondent), pursuant to Section 120.569, and 120.57, Florida Statutes, (2017), and alleges:

NATURE OF THE ACTION

This is an action to impose administrative fines in the amount of twelve thousand eight hundred dollars ($12,800.00) pursuant to Sections 120.569, 120.57, 395.1055 and 395.1065, Fla. Stat. (2018).

JURISDICTION AND VENUE

1. The Agency has jurisdiction pursuant to Chapters 395, Part I, and 408, Part II, Fla. Stat. (2018).

2. Venue lies pursuant to Section 120.57 Florida Statutes, and Chapter 28-106.207 Florida Administrative Code.

EXHIBIT 1

PARTIES

3. The Agency is the regulatory authority with regard to hospital licensing and regulation pursuant to Chapters 395, Part I, and 408, Part II, Florida Statutes, and Chapter 59A-3, Florida Administrative Code, respectively.

4. Respondent is a hospital located at 1 Tampa General Circle, Tampa, Florida 33606, and is licensed under Chapter 395, Part I, Florida Statutes and Chapter 59A-3, Florida Administrative Code, license number 4044.

5. Respondent was at all times material hereto a licensed facility under the licensing authority of the Agency, and was required to comply with all applicable rules, and statutes.

COUNT I

6. The Agency re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.

7. That Florida law provides:,

> (3) Each hospital shall maintain a current and complete medical record for every patient seeking care or service. The medical record shall contain information required for completion of birth, death and still birth certificates, and shall, contain the following information:
> (a) Identification data;
> (b) Chief complaint or reason for seeking care;
> (c) Present illness;
> (d) Personal medical history;
> (e) Family medical history;
> (f) Physical examination report;
> (g) Provisional and pre-operative diagnosis;
> (h) Clinical laboratory reports;
> (i) Radiology, diagnostic imaging, and ancillary testing reports;
> (j) Consultation reports;
> (k) Medical and surgical treatment notes and reports;
> (l) Evidence of appropriate informed consent;
> (m) Evidence of medication and dosage administered;
> (n) A copy of the Patient Care Record, in accordance with subsection 64J-1.001(18),

F.A.C., if the patient was delivered to the hospital by ambulance;
(o) Tissue reports;
(p) Physician, APRN, PA and nurse progress notes;
(q) Principal diagnosis, secondary diagnoses and procedures when applicable;
(r) Discharge summary;
(s) Appropriate social work services reports, if provided;
(t) Autopsy findings when performed;
(u) Individualized treatment plan;
(v) Clinical assessment of the patients needs;
(w) Certifications of transfer of the patient between hospitals as specified by rule 59A-3.255, F.A.C.; and,
(x) Routine Inquiry Form regarding request for organ donation in the event of the death of the patient.
Rule 59A-3.270(3), Florida Administrative Code.

8. That on March 8. 2018, the Petitioner Agency completed a licensure complaint survey of the Respondent facility.

9. That based upon the review of records and interview, Respondent failed to ensure the accuracy of the medical record for one (1) of twelve (12) sampled patients, the same being contrary to the mandates of law.

10. That Petitioner's representative reviewed Respondent's records related to patient number ten (10) and noted the Operative Report, dated December 26, 2017, and signed by the attending surgeon indicated the ECMO (Extracorporeal Membrane Oxygenation) catheter that was providing oxygenated blood to the patient was inadvertently removed from the patient when the scrub tech removed the surgical drapes.

11. That Petitioner's representative interviewed on March 6, 2018 at approximately 11:00 a.m. Respondent's certified scrub technician first assist (CSTFA) and registered nurse (RN) circulator that were present in the operating room on December 26, 2017 when the catheter was pulled from patient number ten (10) and the personnel indicated:

a. The scrub technician stated that as the patient was being taken out of the operating

room to the intensive care unit, the surgeon asked her to "remove it," and she thought he meant for her to take out the extracorporeal membrane oxygenation catheter.

b. The technician did not clarify the surgeon's orders and subsequently removed the newly revised extracorporeal membrane oxygenation catheter, which resulted in massive bleeding.

c. The technician stated she had pulled out the right femoral line and knew immediately after she pulled out the line it was the one being used for the extracorporeal membrane oxygenation.

d. The technician was not aware this was the newly revised extracorporeal membrane oxygenation catheter that had just been placed because she came in to provide a lunch break for another staff member towards the end of the case.

12. That Petitioner's representative reviewed the operative report for patient number ten (10) which reflected that the certified scrub technician first assist entered the operating room at 12:14 p.m., and the case started at 9:55 a.m. and ended at 12:38 p.m.

13. That Petitioner's representative interviewed Respondent's registered nurse (RN) circulator that entered the operating room at 11:55 a.m. during the procedure on patient number ten (10) who indicated:

a. He was not present for the entire case and was providing a lunch break for another staff member.

b. As the patient was being taken out of the operating room and back to the intensive care unit, the certified scrub technician first assist pulled out the newly placed femoral cannula and the patient began to bleed.

c. The perfusionist told him the patient was bleeding out.

d. "The CSTFA that pulled the line was holding pressure on the groin. The anesthesiologist instructed us to defibrillate per the monitor, which we did with no result. The CSTFA and I started CPR."

e. He had been in the room for approximately thirty to thirty-five minutes before the patient required cardiopulmonary resuscitation.

14. That Petitioner's representative interviewed on March 5, 2018 at approximately 5:00 p.m. Respondent's chief quality officer who confirmed the finding the Operative Report was not accurate.

15. That the above reflects Respondent's failure to ensure the accuracy of the medical record for patient number ten (10).

16. That the Agency cited the Respondent facility for the above referenced deficiency.

17. That the above cited deficiency subjects the Respondent facility to the imposition of an administrative penalty in a sum not to exceed one thousand dollars ($1,000.00) per violation per day. § 395.1065 (2)(a) Fla. Stat. (2017).

WHEREFORE, the Agency intends to impose an administrative fine in the amount of one thousand dollars ($1,000.00) against Respondent, a hospital in the State of Florida, pursuant to § 395.1065 (2)(a) Fla. Stat. (2017).

COUNT II

18. The Agency re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.

19. That pursuant to Florida law:

(1) Each hospital shall establish an infection control program involving members of the organized medical staff, the nursing staff, other professional staff as appropriate, and

administration. The program shall comply with the requirements in Sections 381.0098 and 395.1011, F.S. and shall provide for:
(a) The surveillance, prevention, and control of infections among patients and personnel;
(b) The establishment of a system for identifying, reporting, evaluating and maintaining records of infections;
(c) Ongoing review and evaluation of all septic, isolation and sanitation techniques employed in the hospital; and,
(d) Development and coordination of training programs in infection control for all hospital personnel.
Rule 59A-3.250(1), Florida Administrative Code.

20. That on March 8. 2018, the Petitioner Agency completed a licensure complaint survey of the Respondent facility.

21. That based upon the review of records and interview, Respondent failed to maintain an infection control program that minimizes risk of infections associated with procedures performed by the facility, the same being contrary to the requirements of law.

22. That Petitioner's representative reviewed Respondent's policy and procedure entitled, "Use of Substerile Autoclaves," #F-1, revised 09/2016, and noted the following related to perioperative personnel guidance for sterilization practices that eliminate immediate use steam sterilization (IUSS):

a. Immediate use steam sterilization (IUSS) cycles are not permitted.

b. Post-sterilization verification - upon completion of the sterilization cycle the user must verify and document that all parameters and internal integrators for the sterilization load has successfully been met.

c. Documentation - sterilization cycles will be documented within the designating tracking log or system.

d. Monitoring - the use of sub-sterile autoclaves will be routinely monitored and tracked. Documentation compliance will be reviewed and reported to the

appropriate Surgical Service leaders.

23. That Petitioner's representative toured Respondent's Cardiovascular Operating Department, on March 5, 10'8 commencing at approximately 9:40 a.m. accompanied by Respondent's Director of Cardiovascular/Transplant Operating Rooms (CVTOR), who confirmed the department had five autoclaves and during a tour of two sub-sterile rooms between CVOR's 7, 8, and 9 noted as follows:

a. There was a sterilization log dated March 5, 2018 for each autoclave.

b. The log had missing documentation related to what instruments were sterilized, why the instruments were sterilized, and the patient label indicating the type of surgery and surgical instruments IUSS was used for.

c. The rooms each had two oven mitts for removing hot surgical instrument trays from the steam sterilizer and transporting them into the CVOR.

24. That Petitioner's representative interviewed on March 5, 2018 at 11:30 a.m. Respondent's Sterile Processing Department (SPD) Director who indicated:

a. The definition of IUSS was "no shelf life."

b. Some sterilization trays receiving IUSS have between five (5) and eighty (80) surgical instruments in them.

c. The facility does not track, trend, or report out IUSS use to Surgical Services leaders.

25. That Petitioner's representative toured on March 7, 2018 commencing at approximately 9:20 a.m. all operating rooms in the facility, with the exception of the CVOR, accompanied by Respondent's SPD Director, SPD Manager, OR Educator, and OR Manager, and noted:

a. The SPD Director and OR Manager confirmed the following numbers and

locations of the facility steam sterilizers/autoclaves that were observed during the tour:

i. CVOR – nine (9) operating rooms and five (5) steam sterilizers/autoclaves.

ii. Main OR – nineteen (19) operating rooms and ten (10) steam sterilizers/autoclaves.

iii. 3F OR – nine (9) operating rooms and four (4) steam sterilizers/autoclaves.

iv. Women's Surgical – eight (8) operating rooms and two (2) steam sterilizers/autoclaves.

v. Burn Unit – one (1) operating room and one (1) steam sterilizer/autoclave.

b. A total of twenty-two (22) steam sterilizers are located in the facility OR's (SPD not included).

26. That on March 7, 2018 at approximately 10:00 a.m., while on tour of the main OR's, Petitioner's representative interviewed Respondent's OR Manager related to the process steps involved with steam sterilization of surgical instruments and the Manager indicated the following:

a. All loads of surgical instruments must be documented on the Surgical Services Sterilization Log.

b. The log is daily log. There is a log for each day of the month.

c. The staff are to document the OR number, time the cycle ran, identification of the employee performing the sterilization, and what surgical instruments the load

contained.

d. Once the sterilization cycle is complete, the oven mittens are used to take the surgical instrument tray out of the steam sterilizer and into the surgical suite.

e. Oven mittens are used because the surgical instrument trays come out of the sterilizer hot.

f. Approximately 160-180 of the operating Registered Nurses (RN's) and Surgical Technicians (ST) perform sterilization of surgical instruments.

27. That Petitioner's representative interviewed Respondent's OR educator on March 7, 2018 at approximately 10:05 a.m. who confirmed the above recited findings related to IUSS.

28. That Petitioner's representative reviewed on March 7, 2018 at approximately 10:45 a.m. Respondent's February 2018 Surgical Services Steam Sterilization daily logs and noted:

a. There were multiple instrument loads with no patient label or indication of what and why the instruments were sterilized.

b. There were multiple daily logs without documentation of whether the load passed or failed sterilization parameters.

29. That Petitioner's representative requested Respondent tabulate the IUSS rate and missing documentation frequency on the daily sterilization logs for December 2017 through February 2018.

30. That Petitioner's representative was provided by Respondent's SPD Director on March 7, 10`8 at approximately 3:00 p.m. the following information related to IUSS from December 2017 through February 2018:

a. IUSS steam sterilization rate in the 9 CVOR's averaged 6.0%; indicating approximately 77 loads of instruments were steam sterilized for immediate use.

b. IUSS steam sterilization rate in the 38 OR's, excluding the CVOR, averaged 6.0%.

c. In the month of February 2018 the facility performed approximately 2,795 surgeries with an IUSS rate of 6.9 %, indicating approximately 192 loads of instruments were steam sterilized for immediate use.

d. Total number of steam sterilization loads with no indication if sterilization parameters were met - 220 (96.6%).

e. Total number of steam sterilization loads with no patient label - 150 (66%).

f. Total number of steam sterilization loads with no room number - 26 (11%).

g. Total number of steam sterilization loads with no time indicated - 41 (18%)

h. Total number of steam sterilization loads with no employee identification 19 (8%).

i. Total IUSS logs not compliant - 228 (46%).

31. That Petitioner's representative confirmed these numbers with Respondent's SPD Director on March 8, 2018 at approximately 3:50 p.m.

32. That on March 5, 2018 at approximately 1:45 p.m., Petitioner's representative reviewed Respondent's policy and procedure entitled, "Legionella", #IC-17, and effective 11/2010, and noted as follows:

a. The Facilities Department is responsible for the development and review of a Legionella prevention plan and disinfection of potable water in the event a Legionella case.

b. The Facilities Department will report significant findings of monitoring to the Infection Prevention Committee on an annual basis.

c. The Infection Prevention Department will assist in the development of the water management plan related to Legionella.

33. That absent from the policy and procedure related to Legionella was the presence of the following, as required by industry standards, for the prevention of Legionella and other opportunistic water pathogens:

a. Facility risk assessment to identify where Legionella and other opportunistic waterborne pathogens (e.g. Pseudomonas, Acinetobacter, Burkholderia, Stenotrophomonas, nontuberculous mycobacteria, and fungi) could grow and spread in the facility's water system.

b. Implementation of a water management program that considers the industry standard and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens.

c. Specification of testing protocols and acceptable ranges for control measures, and documentation of the results of testing and corrective actions taken when control limits are not maintained.

34. That Petitioner's representative interviewed on March 7, 2018 at approximately 3:00 p.m., Respondent's Director of Facilities Management and Senior Engineer Facilities Management who indicated the facility did not currently have a water risk assessment or policy and procedure to reduce the risk of patient exposure to Legionella and other opportunistic pathogens from the facility water systems.

35. That Petitioner's representative reviewed on March 8, 2018 at approximately 10:00 a.m. Respondent's documentation reflecting Respondent's hospital pneumonia's (HAP's) and

associated water pathogens from Jan. 2017 - Dec. 2017 and noted as follows:

a. Legionella – 0.

b. Pseudomonas – 10.

c. Acinetobacter – 2.

d. Burkholderia – 1.

e. Stenotrophomonas – 4.

f. Mycobacteria- nontuberculous – 3.

g. Fungi - Candida albicans – 4.

h. Candida parapsiliosis – 4.

36. That a total of twenty-eight (28) hospital acquired pneumonia's were identified in 2017, which have the potential to be acquired from the facility's water.

37. That Petitioner's representative interviewed on March 8, 2018 at approximately 10:45 a.m. Respondent's Infection Preventionist (IP) who indicated:

a. She confirmed the above findings related to the facility's HAP's in 2017.

b. She had not performed an investigation as to the source of the HAP's at the time they were identified and could not say if they were acquired from the facility water.

c. She had not reported the 2017 HAP's to the Facilities Department leadership.

38. That the above reflects Respondent's failure to maintain an infection control program that minimizes risk of infections associated with procedures performed by the facility.

39. That the Agency cited the Respondent facility for the above referenced deficiency.

40. That the above cited deficiency subjects the Respondent facility to the imposition of an administrative penalty in a sum not to exceed one thousand dollars ($1,000.00) per violation per

day. § 395.1065 (2)(a) Fla. Stat. (2017).

WHEREFORE, the Agency intends to impose an administrative fine in the amount of two thousand eight hundred dollars ($2,800.00) against Respondent, a hospital in the State of Florida, pursuant to § 395.1065 (2)(a) Fla. Stat. (2017).

COUNT III

41. The Agency re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.

42. That Florida law provides:

> (3) Incident Report Review and Analysis. The risk manager shall be responsible for the regular and systematic reviewing of all incident reports including 15-day incident reports for the purpose of identifying trends or patterns as to time, place or persons: and upon emergence of any trend or pattern in incident occurrence shall develop recommendations for corrective actions and risk management prevention education and training. Summary data thus accumulated shall be systematically maintained for 3 years.
> (a) At least quarterly or more often as may be required by the governing body, the risk manager shall provide a summary report to the governing body which includes information about activities of risk management as defined herein.
> (b) Evidence of the incidents reporting and analysis system and copies of summary reports, incident reports filed within the facility, and evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the Agency upon request during normal working hours.
> Rule 59A-10.005(3), Florida Administrative Code.

43. That on March 8. 2018, the Petitioner Agency completed a licensure complaint survey of the Respondent facility.

44. That Based upon observation, the review of documents, and interview, Respondent failed to provide a quarterly summary report to its governing body that includes information about the activities of risk management, the same being contrary to the mandates of law.

45. That Petitioner's representative reviewed Respondent's board of director meeting agendas for January 31, 2017, March 28, 2017, May 30, 2017, August 29, 2017, October 31, 2017, and November 28, 2017 and noted that none of the agendas included a summary report that included activities of risk management.

46. That Petitioner's representative interviewed Respondent's licensed risk manager on March 8, 2018 at 1:00 p.m. who indicated that risk management activities are reported to the board through the quality council.

47. That Petitioner's representative reviewed Respondent's quality council meeting minutes for March 22, 2017, May 24, 2017, August 23, 2017, and November 29, 2017 and noted no recorded information presented to the council that included activities of risk management.

48. That Petitioner's representative interviewed Respondent's risk manager during the survey who indicated as follows:

a. When asked to provide a risk management summary report for review, the risk manager presented a PIE Chart Claims report.

b. The manager indicated that the clinical areas track events pertaining to their areas that is, in most cases, taken from event reports, and this information was presented to the hospital's quality council.

49. That Petitioner's representative reviewed Respondent's Surgical Services Dashboard dated from January through November 2017 and noted the clinical department tracking of items such as retained foreign body, incorrect counts, time out fail, death in the operating room, and unplanned procedures., with the data presented as raw data.

50. Absent from the records presented was any evidence that the information had been trended or analyzed with the goal to improve performance or that any such information was

presented by the risk management department to the board of directors as evidence of risk management activities.

51. That the above reflects Respondent's failure to provide a quarterly summary report to its governing body that includes information about the activities of risk management.

52. That the Agency cited the Respondent facility for the above referenced deficiency.

53. That the above cited deficiency subjects the Respondent facility to the imposition of an administrative penalty in a sum not to exceed one thousand dollars ($1,000.00) per violation per day. § 395.1065 (2)(a) Fla. Stat. (2017).

WHEREFORE, the Agency intends to impose an administrative fine in the amount of four thousand dollars ($4,000.00) against Respondent, a hospital in the State of Florida, pursuant to § 395.1065 (2)(a) Fla. Stat. (2017).

COUNT IV

54. The Agency re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.

55. That Florida law provides:

> Every licensed facility shall, as a part of its administrative functions, establish an internal risk management program that includes all of the following components ... (d) A system for informing a patient or an individual identified pursuant to s. 765.401 (1) that the patient was the subject of an adverse incident, as defined in subsection (5). Such notice shall be given by an appropriately trained person designated by the licensed facility as soon as practicable to allow the patient an opportunity to minimize damage or injury.
> Section 395.0197(d), Florida Statutes (2017).
> ....
> Duty to Notify Patients - An appropriately trained person designated by each licensed facility shall inform each patient, or an individual identified pursuant to s. 765.401 (1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care that result in harm to the patient under this section shall not constitute an acknowledgment or admission of liability, nor

can it be introduced as evidence.
Section 395.1051, Florida Statutes (2017).

56. That on March 8. 2018, the Petitioner Agency completed a licensure complaint survey of the Respondent facility.

57. That based upon the review of records, observation, and interview, Respondent failed to ensure disclosure of an adverse incident resulting in the death of a patient to the appropriate individual as defined by law.

58. That Petitioner's representative reviewed Respondent's records related to patient number ten (10) and noted the Operative Report, dated December 26, 2017, and signed by the attending surgeon indicated the ECMO (Extracorporeal Membrane Oxygenation) catheter that was providing oxygenated blood to the patient was inadvertently removed from the patient when the scrub tech removed the surgical drapes.

59. That Petitioner's representative interviewed on March 6, 2018 at approximately 11:00 a.m. Respondent's certified scrub technician first assist (CSTFA) and registered nurse (RN) circulator that were present in the operating room on December 26, 2017 when the catheter was pulled from patient number ten (10) and the personnel indicated:

a. The scrub technician stated that as the patient was being taken out of the operating room to the intensive care unit, the surgeon asked her to "remove it," and she thought he meant for her to take out the extracorporeal membrane oxygenation catheter.

b. The technician did not clarify the surgeon's orders and subsequently removed the newly revised extracorporeal membrane oxygenation catheter, which resulted in massive bleeding.

c. The technician stated she had pulled out the right femoral line and knew

immediately after she pulled out the line it was the one being used for the extracorporeal membrane oxygenation.

d. The technician was not aware this was the newly revised extracorporeal membrane oxygenation catheter that had just been placed because she came in to provide a lunch break for another staff member towards the end of the case.

60. That Petitioner's representative reviewed the operative report for patient number ten (10) which reflected that the certified scrub technician first assist entered the operating room at 12:14 p.m., and the case started at 9:55 a.m. and ended at 12:38 p.m.

61. That Petitioner's representative interviewed Respondent's registered nurse (RN) circulator that entered the operating room at 11:55 a.m. during the procedure on patient number ten (10) who indicated:

a. He was not present for the entire case and was providing a lunch break for another staff member.

b. As the patient was being taken out of the operating room and back to the intensive care unit, the certified scrub technician first assist pulled out the newly placed femoral cannula and the patient began to bleed.

c. The perfusionist told him the patient was bleeding out.

d. "The CSTFA that pulled the line was holding pressure on the groin. The anesthesiologist instructed us to defibrillate per the monitor, which we did with no result. The CSTFA and I started CPR."

e. He had been in the room for approximately thirty to thirty-five minutes before the patient required cardiopulmonary resuscitation.

62. That Petitioner's representative reviewed the medical record related to patient number ten

(10) during the survey and could locate no evidence that the patient's individual identified in section 765.401(1), Florida Statutes, in this case an adult child, was notified of the adverse incident.

63. That Petitioner's representative interviewed Respondent's risk management specialist on March 5, 2018 at 1:30 p.m. regarding the notification of the appropriate individual related to the adverse incident involving patient number ten (10) who, upon review of the patient's record, confirmed the finding.

64. That the above reflects Respondent's failure to ensure disclosure of an adverse incident resulting in the death of a patient to the appropriate individual.

65. That the Agency cited the Respondent facility for the above referenced deficiency.

66. That the above cited deficiency subjects the Respondent facility to the imposition of an administrative penalty in a sum not to exceed one thousand dollars ($1,000.00) per violation per day. § 395.1065 (2)(a) Fla. Stat. (2017).

WHEREFORE, the Agency intends to impose an administrative fine in the amount office thousand dollars ($5,000.00) against Respondent, a hospital in the State of Florida, pursuant to § 395.1065 (2)(a) Fla. Stat. (2017).

Respectfully submitted this 2 day of October 2018.

Thomas J. Walsh, II
Fla. Bar. No. 566365
Counsel for Petitioner
Agency for Health Care Administration
525 Mirror Lake Drive, Suite 330G
St. Petersburg, FL 33701
727.552.1947 (office)
727.552.1440 (facsimile)
walsht@ahca.myflorida.com

Respondent is notified that it has a right to request an administrative hearing pursuant to Section 120.569, Florida Statutes. Specific options for administrative action are set out in the attached Election of Rights.

All requests for hearing shall be made to the Agency for Health Care Administration, and delivered to ***Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Bldg #3,MS #3, Tallahassee, FL 32308;Telephone (850) 412-3630.***

RESPONDENT IS FURTHER NOTIFIED THAT THE FAILURE TO REQUEST A HEARING WITHIN 21 DAYS OF RECEIPT OF THIS COMPLAINT WILL RESULT IN AN ADMISSION OF THE FACTS ALLEGED IN THE COMPLAINT AND THE ENTRY OF A FINAL ORDER BY THE AGENCY.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been served by U.S. Certified Mail, Return Receipt No. 7004 2510 0001 4448 2916 on October 2, 2018 to Jonathan Dixon III, Esq., Registered Agent for Florida Health Sciences Services Inc., d/b/a Tampa General Hospital, One Davis Boulevard, Suite 401, Tampa, Florida 33606, and by regular U.S. Mail to John Couris, CEO, Florida Health Sciences Services Inc. d/b/a Tampa General Hospital, 1 Tampa General Circle, Tampa, Florida 33606.

Thomas J. Walsh II, Esquire

Copy furnished to:
Patricia Caufman
Field Office Manager
Agency for Health Care Admin.
(Interoffice Mail)

STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION

RE: Florida Health Sciences Services Inc. **AHCA No. 2018007502**
d/b/a Tampa General Hospital

ELECTION OF RIGHTS

This Election of Rights form is attached to a proposed agency action by the Agency for Health Care Administration (AHCA). The title may be Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine or Administrative Complaint. Your Election of Rights may be returned by mail or by facsimile transmission, **but must be filed within 21 days** of the day that you receive the attached proposed agency action. **If your Election of Rights with your selected option is not received by AHCA within 21 days of the day that you received this proposed agency action, you will have waived your right to contest the proposed agency action and a Final Order will be issued.**

(Please use this form unless you, your attorney or your representative prefer to reply according to Chapter120, Florida Statutes, and Chapter 28, Florida Administrative Code.)

Please return your **Election of Rights** to this address:

Agency for Health Care Administration
Attention: Agency Clerk
2727 Mahan Drive, Mail Stop #7
Tallahassee, Florida 32308.
Telephone: 850-412-3630 Facsimile: 850-921-0158

PLEASE SELECT ONLY 1 OF THESE 3 OPTIONS

OPTION ONE (1) _____ I admit to the allegations of facts and law contained in the Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine, or Administrative Complaint and I waive my right to object and to have a hearing. I understand that by giving up my right to a hearing, a final order will be issued that adopts the proposed agency action and imposes the penalty, fine or action.

OPTION TWO (2) _____ I admit to the allegations of facts contained in the Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine, or Administrative Complaint, but I wish to be heard at an informal proceeding (pursuant to Section 120.57(2), Florida Statutes) where I may submit testimony and written evidence to the Agency to show that the proposed administrative action is too severe or that the fine should be reduced.

OPTION THREE (3) _____ I dispute the allegations of fact contained in the Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine, or Administrative Complaint,

and I request a formal hearing (pursuant to Section 120.57(1), Florida Statutes) before an Administrative Law Judge appointed by the Division of Administrative Hearings.
PLEASE NOTE: Choosing OPTION THREE (3), by itself, is NOT sufficient to obtain a formal hearing. You also must file a written petition in order to obtain a formal hearing before the Division of Administrative Hearings under Section 120.57(1), Florida Statutes. It must be received by the Agency Clerk at the address above **within 21 days** of your receipt of this proposed agency action. The request for formal hearing must conform to the requirements of Rule 28-106.2015, Florida Administrative Code, which requires that it contain:

1. The name, address, telephone number, and facsimile number (if any) of the Respondent.
2. The name, address, telephone number and facsimile number of the attorney or qualified representative of the Respondent (if any) upon whom service of pleadings and other papers shall be made.
3. A statement requesting an administrative hearing identifying those material facts that are in dispute. If there are none, the petition must so indicate.
4. A statement of when the respondent received notice of the administrative complaint.
5. A statement including the file number to the administrative complaint.

Mediation under Section 120.573, Florida Statutes, may be available in this matter if the Agency agrees.

License Type: _____ (ALF? Nursing Home? Medical Equipment? Other Type?)

Licensee Name: _____ License Number: _____

Contact Person: _____ Title: _____

Address: _____
Number and Street City Zip Code

Telephone No. _____ Fax No. _____

E-Mail (optional) _____

I hereby certify that I am duly authorized to submit this Election of Rights to the Agency for Health Care Administration on behalf of the licensee referred to above.

Signed: _____ Date: _____

Print Name: _____ Title: _____

STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION

RE: Florida Health Sciences Services Inc. **AHCA No. 2018007502**
d/b/a Tampa General Hospital

ELECTION OF RIGHTS

This Election of Rights form is attached to a proposed agency action by the Agency for Health Care Administration (AHCA). The title may be Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine or Administrative Complaint. Your Election of Rights may be returned by mail or by facsimile transmission, **but must be filed within 21 days** of the day that you receive the attached proposed agency action. **If your Election of Rights with your selected option is not received by AHCA within 21 days of the day that you received this proposed agency action, you will have waived your right to contest the proposed agency action and a Final Order will be issued.**

(Please use this form unless you, your attorney or your representative prefer to reply according to Chapter120, Florida Statutes, and Chapter 28, Florida Administrative Code.)

Please return your **Election of Rights** to this address:

Agency for Health Care Administration
Attention: Agency Clerk
2727 Mahan Drive, Mail Stop #7
Tallahassee, Florida 32308.
Telephone: 850-412-3630 Facsimile: 850-921-0158

PLEASE SELECT ONLY 1 OF THESE 3 OPTIONS

OPTION ONE (1) _____ I admit to the allegations of facts and law contained in the Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine, or Administrative Complaint and I waive my right to object and to have a hearing. I understand that by giving up my right to a hearing, a final order will be issued that adopts the proposed agency action and imposes the penalty, fine or action.

OPTION TWO (2) _____ I admit to the allegations of facts contained in the Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine, or Administrative Complaint, but I wish to be heard at an informal proceeding (pursuant to Section 120.57(2), Florida Statutes) where I may submit testimony and written evidence to the Agency to show that the proposed administrative action is too severe or that the fine should be reduced.

OPTION THREE (3) _____ I dispute the allegations of fact contained in the Notice of Intent to Impose a Late Fee, Notice of Intent to Impose a Late Fine, or Administrative Complaint,

EXHIBIT 2

and I request a formal hearing (pursuant to Section 120.57(1), Florida Statutes) before an Administrative Law Judge appointed by the Division of Administrative Hearings.
PLEASE NOTE: Choosing OPTION THREE (3), by itself, is NOT sufficient to obtain a formal hearing. You also must file a written petition in order to obtain a formal hearing before the Division of Administrative Hearings under Section 120.57(1), Florida Statutes. It must be received by the Agency Clerk at the address above **within 21 days** of your receipt of this proposed agency action. The request for formal hearing must conform to the requirements of Rule 28-106.2015, Florida Administrative Code, which requires that it contain:

1. The name, address, telephone number, and facsimile number (if any) of the Respondent.
2. The name, address, telephone number and facsimile number of the attorney or qualified representative of the Respondent (if any) upon whom service of pleadings and other papers shall be made.
3. A statement requesting an administrative hearing identifying those material facts that are in dispute. If there are none, the petition must so indicate.
4. A statement of when the respondent received notice of the administrative complaint.
5. A statement including the file number to the administrative complaint.

Mediation under Section 120.573, Florida Statutes, may be available in this matter if the Agency agrees.

License Type: Hospital (ALF? Nursing Home? Medical Equipment? Other Type?)

Licensee Name: Tampa General Hospital License Number: 4044

Contact Person: Denise Jones Title: Director of Risk Managem

Address: 1 Tampa General Circle (Number and Street) Tampa, FL (City) 33606 (Zip Code)

Telephone No. 813-844-7666 Fax No. 813-844-4569

E-Mail (optional) _____

I hereby certify that I am duly authorized to submit this Election of Rights to the Agency for Health Care Administration on behalf of the licensee referred to above.

Signed: _____ Date: 10/19/15

Print Name: _____ Title: _____