



State of New Jersey
DEPARTMENT OF HEALTH
OFFICE OF EMERGENCY MEDICAL SERVICES
PO BOX 360
TRENTON, N.J. 08625-0360

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

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JUDITH M. PERSICHILLI, RN, BSN, MA
Acting Commissioner

December 10, 2019

Dr. Karen Montalto
Dean of Health Sciences
Rowan College at Burlington County
900 College Circle
Mount Laurel, New Jersey 08054

Ms. Debra Moran
Vice President
Virtua Health System
523 Fellowship Rd.
Suite 270
Mt. Laurel, NJ 08084

Re: **Corrective Action Plan Approval of Paramedic Clinical and Didactic Training Sites: Investigation Control #2018-0108V**

The New Jersey Department of Health (the Department) is vested with the responsibility of carrying out the provisions of N.J.S.A. 26:2H-1, et seq., Health Care Facilities Planning Act, which was enacted, in part, to ensure that all hospital and related health care services rendered in the State of New Jersey are of the highest quality. As defined at N.J.S.A. 26:2H-2b, health care services include paramedical services. In furtherance of the objectives set forth in the statutes, the Department has adopted regulations that govern the training and certification of paramedics, N.J.A.C. 8:41A-1.1, et seq., Emergency Medical Technicians-Paramedic: Training and Certification.

As defined in N.J.A.C. 8:41A, paramedic education is comprised of two distinct components including didactic education and clinical training. To achieve this end, the Department authorizes a joint college/mobile intensive care hospital paramedic education program with Rowan College of Burlington County performing the didactic portion and Virtua Health performing the clinical portion. These two components are collectively referred to as the Rowan-Virtua Health Mobile Intensive Care Paramedic Program (the Program).

BACKGROUND:

On May 11, 2018, the New Jersey Department of Health, Office of Emergency Medical Services (OEMS), received correspondence from the Program requesting a waiver of the 36-month education period limit for Student B.M., due to a military deployment. After a cursory review of B.M.'s paramedic education timeline, OEMS requested the Program provide a copy of B.M.'s education file for a full review. After several requests, a partial education file was received and determined to be incomplete. Subsequently, to obtain a full education file, OEMS conducted an in-person mobile intensive care paramedic program audit on July 23, 2018. During the audit, the Program was unable to produce education files for B.M. and multiple other students. It was not until three months following the original waiver request that OEMS finally received B.M.'s full education file on August 3, 2018.

On August 20, 2018, the OEMS received correspondence from the Program requesting six waivers for currently enrolled students. While reviewing the student files, it was discovered that none of the students' records were complete in meeting the requirements of N.J.A.C. 8:41A-2.6 (a)10. It was also discovered that the Program had approved these same six students with incomplete requirements to take the National Registry of Emergency Medical Technicians (NREMT) cognitive examination prior to requesting and obtaining OEMS waivers, which is a violation of the Department's rules and NREMT policies. Five of the six students took the NREMT cognitive examination anyway. OEMS then notified NREMT that these five students failed to meet minimum requirements to sit for the exam. Thereafter, NREMT notified the students that results of their examinations were withheld and their accounts had been placed on hold pending formal notification by OEMS.

Given the above findings, OEMS reviewed the Program's request for paramedic student waivers in 2017 and discovered an additional nine students who were permitted to sit for the NREMT Cognitive Examination prior to meeting all the requirements to do so.

The Department determined that Virtua Health's clinical and Rowan College at Burlington County's didactic education must make extensive corrective actions to said Program.

Below is a summation from the investigation previously outlined in the Department's original correspondence dated October 16, 2018 (Appendix A) that showed serious violations and deficiencies with the paramedic education program that placed public health and safety at risk. The violations include N.J.A.C. 8:41A-2.6 (a)10 and N.J.A.C. 8:41A-2.4 through 2.7:

1. Students failed to meet minimum required hours and/or skills for clinical education.
2. Students permitted to proceed in clinical rotations without successfully completing or meeting competencies.
3. Failure to comply with field experience requirements.
4. Failure of the program's EMS educators to properly discharge their duties and responsibilities.
5. Discrepancies and inconsistencies of student records.
6. Failure of Medical Director oversight.

Shortly thereafter, Rowan College of Burlington County and Virtua Health hired the consulting firm 579 Solutions to which the consultant worked with the Program to develop a

comprehensive corrective action plan to address the violations outlined in Appendix A. Additionally, the consultant was directed by the Program to ensure that each student meets all regulatory requirements to sit for the NREMT examination and to confirm that each individual student meet competency standards to guarantee the public would not be placed at risk. Furthermore, the Program agreed to not accept additional cohorts into the Program until a corrective action plan was developed and approved by the Department.

CONCLUSION

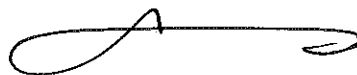
On December 3, 2019, the Program met with OEMS and presented the Program's corrective action plan. As a result of the meeting, OEMS agreed to accept the corrective action plan put forth by the Program. Additionally, OEMS agreed to accept the Program's desire to admit new students into the Program commencing in January 2020. As such, the Department places the following as conditions of approval of the corrective action plan:

1. Submit quarterly compliance plan reports outlining continual monitoring and auditing practices to ensure identified violations of the New Jersey Administrative Code, N.J.A.C. 8:41A-1.1, *et seq.* are not repeated. The quarterly reports shall commence on April 1, 2020 and be submitted at the end of each quarter (June 30, September 30 and December 31, respectively). The quarterly reports shall continue until all of the students in the new cohort beginning in January 2020 have successfully completed or dropped from the program.
2. Established remediation plan in the event the paramedic education program fails to adhere to regulatory requirements, including any policies and procedures of the paramedic education program, [federal] and state laws, regulations and accrediting and licensing standards relevant to the paramedic education program.

Furthermore, due to the egregious violations, and to ensure that the Program is committed to ensuring compliance, the Department *strongly encourages* the Program to continue to employ a consultant for a minimum of one new cohort to ensure effective transition of newly hired program staff and to confirm compliance with state regulations.

If you have any questions concerning this matter, please do not hesitate to contact Dr. Terry Clancy at (609) 376-8735.

Sincerely,



Scot Phelps, JD, MPH, Paramedic
Director
Emergency Medical Services

Attachment

c: Dr. Terry Clancy, OEMS
George Hatch, Committee on Accreditation of Educational Programs for the EMS Professions (CoAEMSP)
Christopher Neuwirth, PHILEP
Mark Terry, National Registry of Emergency Medical Technicians (NREMT)

APPENDIX A



State of New Jersey

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SHEREEF M. ELNAHAL, MD, MBA
Commissioner

October 16, 2018

Dr. Karen Montalto
Dean of Health Sciences
Rowan College at Burlington County
900 College Circle
Mount Laurel, New Jersey 08054

Mr. Anthony Cascio
Program Director
Virtua Health System
523 Fellowship Rd.
Suite 270
Mt. Laurel, NJ 08084

Re: **Notice of Corrective Action of Paramedic Clinical and Didactic Training Sites: Investigation Control #2018-0108V**

Dear Dr. Montalto and Mr. Cascio:

The New Jersey Department of Health (the Department) is vested with the responsibility of carrying out the provisions of N.J.S.A. 26:2H-1, et seq., Health Care Facilities Planning Act, which was enacted, in part, to ensure that all hospital and related health care services rendered in the State of New Jersey are of the highest quality. As defined at N.J.S.A. 26:2H-2b, health care services include paramedical services. In furtherance of the objectives set forth in the statutes, the Department has adopted regulations that govern the training and certification of paramedics, N.J.A.C. 8:41A-1.1, et seq., Emergency Medical Technicians-Paramedic: Training and Certification.

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On August 20, 2018, the OEMS received correspondence from the Program requesting six waivers for currently enrolled students. While reviewing the student files, it was discovered that none of the students' records were complete in meeting the requirements of N.J.A.C. 8:41A-2.6 (a)10. It was also discovered that the Program had approved these same six students with incomplete requirements to take the National Registry of Emergency Medical Technicians (NREMT) cognitive examination prior to requesting and obtaining OEMS waivers, which is a violation of the Department's rules and NREMT policies. Five of the six students took the NREMT cognitive examination anyway. OEMS then notified NREMT that these five students failed to meet minimum requirements to sit for the exam. Thereafter, NREMT notified the students that results of their examinations were withheld and their accounts had been placed on hold pending formal notification by OEMS.

Given the above findings, OEMS reviewed the Program's request for paramedic student waivers in 2017 and discovered an additional nine students who were permitted to sit for the NREMT Cognitive Examination prior to meeting all the requirements to do so.

The Department has determined that Virtua Health's clinical and Rowan College at Burlington County's didactic education must make extensive corrective actions to said Program.

Below are details from the investigation that show serious violations and deficiencies with the paramedic education program that place public health and safety at risk. The violations include N.J.A.C. 8:41A-2.6 (a)10 and N.J.A.C. 8:41A-2.4 through 2.7 including the following:

VIOLATION: STUDENTS FAILED TO MEET MINIMUM REQUIRED HOURS AND/OR SKILLS FOR CLINICAL EDUCATION

Most concerning, the investigation revealed that the Program's students are not being monitored to ensure that clinical education hours and/or the minimum number of

skills required under N.J.A.C. 8:41A-2.4 through 2.7 are in fact completed. N.J.A.C. 8:41A-2.4 provides that paramedic students must complete a minimum of 700 hours of total clinical education, which is broken up as follows:

- i. Emergency Department (ED): 100 hours;
- ii. Intensive/Coronary Care Units (ICU/CCU): 40 hours;
- iii. Operating/Recovery Room (OR): 24 hours;
- iv. IV Therapy Team, if available: 16 hours;
- v. Pediatric Unit: 40 hours;
- vi. Labor/Delivery/Newborn Nursery: 24 hours;
- vii. Psychiatric Unit or Crisis Center: Eight hours;
- viii. Cardiology Laboratory: Eight hours; and
- ix. Morgue: Eight hours;
- x. Laboratory: Eight hours; and
- xi. Respiratory Therapy: 24 hours;
- xii. Field experience: 400 hours.

Within each clinical area identified above, each student must perform specific skills and must successfully complete a certain number of the skills in order to demonstrate competence in these areas. See N.J.A.C. 8:41A-2.5, 2.6 and 2.7. For example, a student must successfully perform a series of endotracheal intubations utilizing appropriate equipment and techniques during his or her Operating/Recovery Room education experience. N.J.A.C. 8:41A-2.5(d)(1). And, for the Labor/Delivery/Newborn Nursery education experience, the student must document the observation of at least five vaginal deliveries and identify the normal stages of labor. N.J.A.C. 8:41A-2.6(b)(1) and (2).

Below, please find some notable deficiencies/violations of the students audited who were permitted to sit for the NREMT cognitive exam:

Student S.H.

- No evidence of clinical competency in Rapid Sequence Intubation (RSI)
- Advanced Cardiac Life Support (ACLS) completed *after* Cardiac Catheterization & Cardiac Laboratory rotations
- 1 out of 5 required participations in cardiac arrests
- No evidence of clinical competency examinations in each category of clinical education
- No evidence of a terminal competency examination
- No evidence of clinical competency in central venous access, infusion pumps or AV shunt
- No evidence of clinical competency in RSI
- No evidence of clinical competency in cricothyroidotomy

Student B.M.

- No evidence of clinical competency examinations in each category of clinical education
- No evidence of a terminal competency examination
- No evidence of clinical competency in Rapid Sequence Intubation (RSI)
- No morgue rotation documented
- No evidence that the proper technique for oral suctioning, nasal suctioning, Nasopharyngeal Airway (NPA), Oropharyngeal Airway (OPA), Endotracheal Tube (ETT), Laryngeal Mask Airway (LMA), or alternative airways were performed during the Respiratory rotation
- No evidence of a Trauma case study
- No evidence of a Pediatric case study
- No evidence of an ICU/CCU case study
- 2 out of 5 patients suctioned with an ETT
- No evidence of verified patient histories and assessments in the ICU, CCU, or Emergency Department
- No evidence of verified neurological assessments in the ICU, CCU, or Emergency Department
- No evidence of verified trauma assessments in the ICU, CCU, or Emergency Department
- No evidence of proper Intramuscular, Subcutaneous, Sublingual, Topical, or, Intraosseous medication administration in the ICU, CCU, or Emergency Department
- No evidence of proper application and utilization of an external cardiac pacemaker or Automatic External Defibrillator (AED) in the ICU, CCU, or Emergency Department
- 1 out of 5 required participations in cardiac arrests
- No evidence of defibrillations/cardioversions
- No evidence of clinical competency in needle chest decompression
- No evidence of clinical competency in central venous access, infusion pumps or AV shunt
- No evidence of clinical competency in cricothyroidotomy
- No evidence of clinical competency in RSI
- 1 of 5 pediatric patient histories and assessments verified
- No evidence of verified vaginal deliveries
- No psychiatric case study or observation of crisis interview/intervention verified
- 16 of 24 required hours completed in IV Therapy/Laboratory
- 15 of 24 required hours completed in the Operating Room
- 24 of 40 required hours completed in the Pediatric Unit
- 8 of 24 required hours completed in Labor and Delivery

Student P.D.

- No evidence of clinical competency examination in each category of clinical education
- No morgue rotation documented
- No evidence that the proper technique for oral suctioning, nasal suctioning, NPA, OPA, LMA or alternative airway devices were performed during the Respiratory rotation
- No evidence of an ICU case study
- 2 out of 5 required participations in cardiac arrests
- No evidence of clinical competency in needle chest decompression
- No evidence of clinical competency in cricothyroidotomy
- No evidence of a terminal competency examination
- No evidence of clinical competency in RSI

Student R.L.

- Completed 89 hours of the required 100 hours in the Emergency Department clinical rotation
- No evidence of clinical competency in needle chest decompression
- No evidence of clinical competency in RSI
- No evidence of clinical competency in cricothyroidotomy
- No evidence of clinical competency in orogastric tube insertion
- No evidence of clinical competency in central venous access, infusion pumps or AV shunt
- ACLS completed *after* completion of Cardiac Cath and Cardiac Laboratory rotations
- No evidence of clinical competency examination in each category of clinical education
- No evidence of a pediatric case study
- 15 out of 20 required IV infusions documented during IV Therapy Team rotation
- No evidence that the proper technique for nasal suctioning, NPA, OPA or LMA were performed during the Respiratory rotation
- 2 out of 5 required defibrillations/cardioversions with no waiver requested
- No morgue rotation documented
- No evidence of a terminal competency examination

As you should already be aware, the minimum education requirements that each student must complete in the clinical areas outlined above ensure students are competent, accountable and consistent in the provision of care. Indeed, the importance of these minimum requirements is emphasized in N.J.A.C. 8:41A-2.8(a)(2), which states that enforcement action will be taken against a training program that fails to strictly adhere to the training program curriculum. Here, Virtua Health's failure to adhere to the minimum Mobile Intensive Care paramedic education standards not only places the

public's health, safety and welfare at risk, as the students do not have sufficient education to care for critically ill patients in this State, but also places the students in the unfortunate position of having to provide care without the necessary educational tools to provide appropriate care. Even more, the Program's failure to comply with the requirements shows that there was a lack of oversight of its Mobile Intensive Care paramedic students during their clinical education. Thus, the Program has demonstrated an inability to comply with the minimum clinical education requirements for its paramedic students, as set forth in N.J.A.C. 8:41A-2.4 through 2.7.

VIOLATION: STUDENTS PERMITTED TO PROCEED IN CLINICAL ROTATIONS WITHOUT SUCCESSFULLY COMPLETING OR MEETING COMPETENCIES

The investigation also revealed that all four of the Mobile Intensive Care paramedic student files audited were permitted to participate in varying clinical rotations and not in chronological order. As set forth in N.J.A.C. 8:41A-2.1(a) and 2.3(d)(1), paramedic training is made up of two parts: didactic training and clinical training. The clinical training is further broken down into three categories: Category I/Skills Division; Category II/Special Care Division; and Category III/Field Experience. See N.J.A.C. 8:41A-2.5, 2.6 and 2.7.

To ensure that students have the necessary knowledge sets to perform paramedic duties, students must first successfully complete the didactic portion of training, which is textbook and simulated skills training in the classroom, before proceeding to clinical training. N.J.A.C. 8:41A-2.4(d). Once the didactic portion is successfully completed, the student is permitted to proceed to Category I clinical training, which is where the student applies the knowledge he or she gained in the classroom to patients in a controlled hospital setting overseen by medical professionals. Ibid. After successfully completing Category I, the student is then permitted to proceed to Category II clinical training, which is training also conducted under supervision in the hospital setting. See N.J.A.C. 8:41A-2.5(f). Once the student successfully completes the necessary clinical hours and skills in the hospital and demonstrates competencies in all clinical areas under Categories I and II, the student is then permitted to proceed to Category III, which is where the student rides on a mobile intensive care unit and applies his or her newly gained skills in the field while being closely supervised by experienced paramedics. N.J.A.C. 8:41A-2.6(e) and - 2.7. After completing the requirements of each Category, the student is to demonstrate competency in all clinical areas prior to advancing to the next Category of training. The education progresses in this manner so to provide the student with a proper foundation for a Mobile Intensive Care paramedic to practice and cannot be unilaterally altered by an education program.

In the instant matter, the Program failed to comply with this education progression as it has permitted students to jump from one category to the next without completing said Category. Furthermore, there was no evidence of clinical competencies for each Category prior to moving to the next Category.

VIOLATION: FAILURE TO COMPLY WITH FIELD EXPERIENCE REQUIREMENTS

The investigation further revealed that the program has not been complying with field experience requirements. Pursuant to N.J.A.C. 8:41A-2.7(a)(1), paramedic students that are in the field must complete patient care reports for each patient that the student treats or assesses. The investigation showed that the students' reports did not match the medical record. The program consistently failed to monitor students during the field and track students' progress through quality assurance and evaluation methods. Consistently, times and skills documented by the student were not validated by the program, making it difficult to discern if the student met regulatory requirements.

VIOLATION: FAILURE OF THE PROGRAM'S EMS EDUCATORS TO PROPERLY DISCHARGE THEIR DUTIES AND RESPONSIBILITIES

The investigation further showed that the Program's EMS Educators, Matthew Scott, Janis McManus, Ginger Burke, and Michael Kolczynski, who all participated in the audit, have not been discharging their duties and responsibilities as set forth in N.J.A.C. 8:41A-2.4(c). Specifically, N.J.A.C. 8:41A-2.4(c)(7) provides that an EMS Educator is responsible for "developing a final evaluation examination covering all the objectives of the clinical training" and ensuring that each student passed the "examination prior to receiving endorsement to take the NREMT-Paramedic Certification Examination." And, N.J.A.C. 8:41A-2.4(c)(8) states that an EMS Educator is responsible for "[e]nsuring that all students perform and demonstrate competency in all required skills prior to endorsing the student to sit for the NREMT-Paramedic Certification Examination." The investigation revealed that the program's EMS Educators failed to verify student competencies upon completion of their clinical experiences and permitted students to progress through the Program when students failed cognitive exams with *no evidence of remediation*. Additionally, student files lacked oversight during the field experience as evidenced by no quality assurance or remediation evident in student files. Furthermore, students repeatedly failed exams, yet no remediation was evident and were permitted to progress in the Program. Even more, the Educators endorsed the students to sit for the NREMT exam even though their files showed that they did not meet the requirements necessary for such endorsement.

Additionally, N.J.A.C. 8:41A-2.4(c)(4) requires an EMS Educator to provide "each student with at least four periodic written or verbal evaluations." There was no documentation within any the student files reviewed evidencing that these evaluations were conducted.

Based upon the foregoing, the Program's EMS Educators failed to discharge their duties and responsibilities, thereby leaving their paramedic students without proper and adequate oversight. As such, the Program is in violation of N.J.A.C. 8:41A-2.4(c).

VIOLATION: DISCREPANCIES AND INCONSISTENCIES OF STUDENT RECORDS

As a paramedic education institution, the Program is required to "maintain accurate records of the students' progress, documenting satisfactory completion of all clinical objectives." N.J.A.C. 8:41A-2.4(b)(2)(ii). A review of the students' files revealed that the program student recordkeeping system is non-compliant with this requirement as the students' clinical records contain discrepancies, inconsistencies and possibly falsification.

After reviewing files and conducting the audit, OEMS investigators learned that the Program maintains both a paper and electronic tracking system (FISDAP) for tracking student clinical education, both of which contain discrepancies, inconsistencies and fail to reconcile with one another. Most notably, logs did not match the entries contained in FISDAP.

In utilizing FISDAP, students keep track of their own clinical education. The entries made by students into FISDAP were not verified by educators during field time rotations. OEMS investigators reviewed the FISDAP records for the students and found that the entries in FISDAP failed to reconcile with the entries made in the student's logs.

The above described inconsistencies and discrepancies in the Program's recordkeeping system violates N.J.A.C. 8:41A-2.4(b)(2)(ii) and demonstrates the Program's lack of oversight of its Mobile Intensive Care paramedic students during their clinical education. Without consistent, proper documentation, the Program cannot verify that each of its Mobile Intensive Care paramedic students met the minimum regulatory requirements necessary for endorsement for the NREMT exam.

VIOLATION: FAILURE OF MEDICAL DIRECTOR OVERSIGHT

As per N.J.A.C. 8:41A-2.4(b)(1), clinical education sites shall have a Medical Director responsible for overseeing the education and other such information in said Mobile Intensive Care paramedic program. OEMS found no evidence of Medical Director involvement. In fact, during the face to face audit, staff admitted that the Medical Director "trusted" clinical education staff to determine if Mobile Intensive Care paramedic students were competent. Therefore, the Medical Director failed to oversee the education and terminal competencies of said paramedic students.

CONCLUSION

As a result of the above-noted violations found during the audit, OEMS is requiring the Rowan-Virtua Health Mobile Intensive Care Paramedic Program to submit a detailed corrective action plan within 30 days of the date of this letter. At a minimum, the detailed corrective action plan shall address the points outlined in the attached corrective action plan template.

Failure to submit an acceptable corrective action plan within 30 days will result in the Department taking enforcement action against the Program, including but not limited to revocation of the Program's authorization to provide a paramedic training program.

If you have any questions concerning this matter, please do not hesitate to contact Dr. Terry Clancy at (609) 633-7869.

Sincerely,



Scot Phelps, JD, MPH, Paramedic
Director
Emergency Medical Services

Attachment

c: Scott Celli, Virtua Health
Dr. Terry Clancy, OEMS
George Hatch, Committee on Accreditation of Educational Programs for the EMS
Professions (CoAEMSP)
Mark Terry, National Registry of Emergency Medical Technicians (NREMT)

SENT VIA REGULAR US MAIL AND CERTIFIED MAIL #7012 0470 0000 3284 4565
and 7012 2210 0000 7414 7758 RECEIPT REQUESTED