



Colorado Department
of Public Health
and Environment

STATE OF COLORADO

EMERGENCY MEDICAL AND TRAUMA SERVICES



SCOPE OF PRACTICE WAIVER APPLICATION

The Colorado Department of Public Health and Environment (CDPHE) certifies EMS Providers and defines the qualifications and responsibilities of physicians who supervise the performance of EMS Providers. CDPHE, with recommendations from the Emergency Medical Practice Advisory Council (EMPAC), also defines in rule the scope of practice for each EMS Provider level, and providers at each EMS Provider level are limited in their performance by this rule, 6 CCR 1015-3, Chapter Two (the "Practice Rules"). Any skill, procedure or medication that is not expressly permitted in an EMS Provider's scope of practice as defined in the Practice Rules is prohibited unless reviewed by the EMPAC and approved by the CDPHE through the waiver request process.

For a timely and appropriate consideration of your waiver request, please take the time to ensure the accuracy and completeness of this application.

- Section 1 – Medical Director Information
Agency Information
- Section 2 – Waiver Information (including need and support)
- Section 3 – Literature Review (not required on renewals)
- Section 4 – Protocols (including related protocols)
- Section 5 – Training and CQI
- Section 6 – Data (required on all renewals)
- Section 7 – Medical Director Attestation

Completed applications must be received prior to the submission deadline in the format prescribed by the Department.



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SECTION 1 – MEDICAL DIRECTOR AND AGENCY INFORMATION

Medical Director Information

Name (Last, First, MI): Riccio, John C.
 Credentials/Degrees: MD Specialty: Emergency Medicine
 Mailing Address: 980 East Harvard Ave., Stansbury Hall, 2nd Floor
 City: Denver State: CO Zip: 80210
 Primary email: johnriccio@centura.org Secondary email:
 redrockjohn@comcast.net

Have you requested a waiver previously? Yes No

If "Yes", please list the date and type of waiver: Concurrent waivers for droperidol, surgical cricothyroidotomy and single lumen airway. September 2005; RSI for SMFR EMS Supervisors, December 2005; Combitube use for EMT's, June 2007; EMT Basic Use of dual lumen rescue airways, February 2008; Pulse Carbon Monoxide Oximetry, May 2010; Blood Lactate Monitoring for EMT-B-IV, I and P, September 2010; Surgical Airway for SMFR, May 2012; Inapsine, October 2012; Surgical Airway Renewal, Ketamine-April 2013 and renewed in 2016

Agency Information

Agency Name: South Metro Fire Rescue
 Agency Director/Manager: EMS Chief Rick Lewis
 Agency Mailing Address: 9195 E. Mineral Avenue
 City: Centennial State: CO Zip: 80112
 Paid Volunteer Combination
 Certification levels
 # of EMT 335 # of AEMT 0 # of EMT-I 0 # of Paramedics 100

*** - If waiver is to be applied to more than one agency, attach a list with the applicable information to this application.*

Training Center/Group Affiliation

Training Center/Group Name: Centura Health-South Denver Group Prehospital Services
 Training Center/Group # 065- CO
 Address: 980 E. Harvard Ave, Stansbury Hall, 2nd Floor
 City: Denver State: Colorado Zip: 80210



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SECTION 2 – WAIVER INFORMATION AND SUPPORT

Application Type
Initial Renewal Transfer from other Medical Director (list)

Type of Waiver Requested (mark all that apply)
Skill(s)
Medication(s)
Other

Skill Level of Providers Waiver is Applicable To
EMT
AEMT
EMT-I
Paramedic

Waiver Description
Provide a short description of the requested waiver
This waiver application is to permit the use of portable ultrasound sonography in order to evaluate the viability of portable ultrasound in the prehospital environment using a small select group of paramedics in several distinct phases.

Justification / Statement of Need
(may include, but not limited to, the following information)
• Statistics and data including but not limited to: Call volume, prehospital data, hospital data.
• Summary and number of patients who may have benefitted from the proposed waiver.
• Availability or lack of resources.
• Special considerations and its impact on service provision, i.e. weather, traffic, geographic, mutual/auto aid resources
• Estimated cost of implementation
• Description of community partners
The South Metro Fire Rescue Authority (SMFR or Authority) provides prehospital emergency medical care and transportation to 911 patients in the fire jurisdiction comprised of the cities of Centennial, Parker, Sedalia, Castle Pines, Foxfield, Greenwood Villiage, Louviers, Cherry Hills Village, Lone Tree and other nearby jurisdictions of unincorporated Arapahoe and Douglas Counties. The SMFR response area consists of 176 square miles and the residential population is 198,000. SMFR responds to over 19,500 calls per year with up to 10 Advanced Life Support (ALS) ambulances



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and currently also deploys one Advanced Resource Medic car (ARM) that is staffed with a Nurse Practitioner and an advanced trained paramedic. The ARM car provides mobile healthcare services by arriving with the tools necessary to provide advanced medical care in the patient's home environment rather than transporting to a facility. All care provided by the paramedics of SMFR is under the direction of the Medical Director and monitored by the SMFR Authority Quality Assurance group /Quality Improvement Coordinator coupled with Centura Health-South Denver Group Prehospital Services team.

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SECTION 3 – LITERATURE REVIEW

Literature Review

Please provide a brief summary of the applicable literature that would support the need for this waiver request. Include copies of the literature as necessary as an attachment to this application.

This waiver is being sought to permit the use of ultrasound sonography in the prehospital environment by a specially trained cadre of paramedics from the South Metro Fire Rescue Authority. The initial pilot program would determine the practicality and feasibility of the use of prehospital ultrasound with an eye towards possible expansion agency-wide at a later date assuming the feasibility is borne out.

The use of ultrasound in the hospital setting has been around since Karl Dussik attempted to visualize brain tumors in 1942. However, the field of echocardiography really did not come into its' own until 1965 with the introduction of the first real-time ultrasound scanners since previous versions were merely still frame photos. Just as computers technology has progressed and enabled the size to get smaller with faster processing capability, the portable ultrasound machines have evolved correspondingly. Most modern point –of-care ultrasound units are around the same size as a laptop or a tablet computer with several units that are simply transducers that plug into an over the counter smartphone or tablet.

Thus far the adoption of ultrasound in the prehospital arena has been met with varying degrees of success. The use of point-of-care ultrasound in the prehospital setting is a relatively new application. Small studies have shown utility in military, ground, and helicopter EMS services in both Europe and the United States.(1-17) . It is worth noting that several of the studies referred to the use of ultrasound by European EMS models which typically have different staffing models than that are employed in the United States. For example in Germany the German Air Rescue Organization (Deutsche Rettungsflugwacht) as well as several ground based services in Darmstadt and Frankfurt which have incorporated ultrasound into their field management algorithms since 2002-2003. However these units are typically staffed with a combination of emergency physicians and paramedics (15-16). Similarly the French EMS service, SAMU (Service d'Aide Medicale d'Urgence) has employed the use of prehospital ultrasound in the aeromedical setting as far back as 1998. (20). The Italians began using ultrasound in the prehospital setting in 2005 (15). Again the staffing configurations in France and Italy employed physicians in addition to paramedics.

As previously mentioned, EMS services in the US has been slow to adopt the use of prehospital ultrasound as the typical USA focus is on rapid transport and limiting on-scene time coupled with the lack of emergency physicians on scene due to the typical staffing configuration of dual paramedics and/ or paramedic –EMT. The USA saw ultrasound implementation in flight systems and then more recently in the ground setting. Ultrasound use has been described in the following systems ;

- Boston EMS
- Austin and Odessa Texas
- Winnemucca, Nevada
- Temple Terrace, Florida



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- California
- HCMS EMS, Minneapolis, Minnesota
- Norfolk, Virginia

Additionally several paramedic programs (Monroe community College paramedic Program in Rochester , NY and ProEMS Paramedic College in Cambridge , MA) are incorporating the use of prehospital into their paramedic curriculum.

One study surveyed EMS medical directors (N=255 returned surveys out of 755 surveys delivered) about the use of prehospital ultrasound in North America (4.1 % reported currently using ultrasound and an additional 21.7% were considering its implementation) and the most commonly cited applications of prehospital ultrasound were the Focused Abdominal Sonography for Trauma (FAST) and assessment of pulseless electrical activity (PEA) arrest (19). Review of the literature reveals indications for ultrasound use include FAST (4, 21), assessment of pulseless electrical activity arrest and termination of resuscitation attempts (22, 23, 24), cardiac tamponade (11, 25), evaluation of pneumothorax (26) , abdominal aortic aneurysm (7, 27) , vascular access and IO line placement (28), endotracheal tube placement (29, 30), fracture identification (31, 32), and identification of pulmonary edema (26, 33).

This waiver is specifically seeking to have the cadre of SMFR paramedics utilize ultrasound in the following applications;

- PEA arrest causes and potential treatment interventions
- Termination of Resuscitation in cardiac arrest
- Pneumothorax evaluation

Previous implementation of ultrasound in the prehospital environment in the USA, particularly with flight teams consisting of flight nurses, paramedics and physicians have undergone various training regimens. The training times from these groups have been identified in several studies (3, 17, 34) as varying from 3 hours up to 7 hours in length along with additional time in a clinical setting. While the French physicians staffing the ground units underwent an 8 hour didactic course and then 25 FAST ultrasound readings that underwent an overview review. The German teams had a similar regimen with a 1 day didactic and hands-on training session (12, 36). For the USA teams, Heegard et al described that a curriculum for non-physician EMS providers that consisted of a 6 hour didactic course for the FAST exam and the AAA , hands on skills training and written examination (1) . Additionally, the paramedics underwent observed structured clinical encounter scenarios. Utilizing this regimen the paramedics were found to have been adequately trained as well as having demonstrated skills and knowledge retention at the 3 month mark post initial training (18) .

Our waiver request/proposal is for the pilot program is have the Advanced Resource Medics and Nurse Practitioners (ARM) (previously described) from the South Metro Fire Rescue Authority attend an ultrasonography class similar to that presented at the Rocky Vista University College of Osteopathic Medicine (RVUCM). The anticipated course curriculum would be a single day course with the first half of the day devoted to the didactic curriculum and the second half of the day devoted to written multiple choice exam and then review of 25 case studies (half on models/ live EMS



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colleagues and the remaining half in the actual clinical environment). The didactic portion would similar to the training format described by Heegaard, et al (1) in the Hennepin County EMS, Minneapolis, MN program in June 2010;

- Physics and image orientation 60 minutes
- FAST Exam 60 minutes
- Case Review of each quadrant 30 minutes
- Abdominal aorta 40 minutes
- Case Reviews of AAA 30 minutes

The initial training will occur on site with the Rocky Vista University College of Osteopathic Medicine (RVUCM) Physician staff instructors (Dr. David Ross DO, FACEP and 4th year RVUCOM ultrasound "student scholars" whom are very well versed in ultrasound) led by Dr. John Kendall, MD from the University of Colorado School of Medicine and Denver Health Medical Center and Dr. Amanda Toney, MD, Director of Pediatric Emergency Ultrasound and Assistant Professor at Denver Health Medical Center. Additional description of the initial and ongoing training and Quality Improvement program are described in additional detail under Section 5: "Training and CQI".

For this pilot program we have chosen to deploy the Philips "Lumify" ultrasound system. This system utilizes a commercially available smart tablet or smart phone that has been loaded with the Philips Lumify app and then a portable transducer (three different transducer models; S4-1, L12-4, and C5-2; with each transducer and cable weighing roughly 152 grams and is smaller than a smartphone) that is connected via a standard USB port to the smartphone or tablet.

Transducer Specifics;

- A. S4-1 broadband sector array; 4 to 1 MHz extended operating frequency range, 2D, color Doppler, M-mode, advanced XRES and multivariate harmonic imaging,
- B. C5-2 broadband curved array transducer; 5-2 MHz extended operating frequency range, 50mm radius of curvature, 2D, color Doppler, M-mode, advanced XRES and multivariate harmonic imaging, Sono CT.
- C. Lumify L12-4 broadband linear array transducer; 12-4 MHz extended operating frequency range , aperture size of 34mm, 2D, steerable color Doppler, M-mode, advanced XRES and multivariate harmonic imaging, SonoCT

Philips provides HIPAA compliant and data encryption for the cloud-enabled storage and sharing of the archived images with PACS, shared networks, and system directories. Software support and updates are also provided in real time.

It is our assertion that the use of the ultrasound in the prehospital setting will be similar to our past experiences with 12-lead EKG. The 12-lead did not, nor does it currently drastically alter our field care however it does dramatically alter things for the patient on the receiving end at the hospital with initiatives like the mobilization of a cath lab team. We suspect that the field ultrasound will alter things accordingly, particularly in the traumatically injured patient. Imagine how the report of a positive ultrasound reading in the abdomen would alter the reception at the hospital. Equally compelling is



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reducing the numbers of transported cardiac arrest patients when a quick ultrasound reveals no cardiac wall motion confirming the need for termination of resuscitative efforts.

Our outcome goal would then be determined by;

1. Can paramedics utilize ultrasonography in the prehospital setting with at least 90% accuracy (as measured by over-read accuracy), adherence to protocols, and was the ultrasound use indicated.
2. Measurement of aggregate on-scene times to determine if the EMS use of sonography extended those on-scene times beyond the acceptable limits established by Denver Metro EMS protocols (less than 20 minutes for "Medical" calls and less than 10 minutes for "Trauma" calls).
3. Does the use of sonography increase the termination of field pronouncement rates in the out-of-hospital cardiac arrest patient? Our hypothesis is that this rate should increase thereby reducing the amount of out-of-hospital cardiac arrest patients transported to the hospital. This would be the only situation where the use of ultrasonography would function as an exclusionary criteria. At no other point would the patient be left on scene based upon an ultrasonography examination.
4. Does the use of sonography alter the number of patients that are transported emergently or non emergently? Our hypothesis is that the use of sonography should reduce the number of emergent transports. Transport destination would not be altered based upon ultrasonography examinations. Transport destinations would remain compliant with established Mile -High RETAC and Denver Metro EMS Protocol destination protocols.

After determining the results of the initial phase of the pilot program to prove that the use of sonography by the small group of trained paramedics, we would seek to expand the program beyond the initial group to include additional paramedics agency wide beyond the ARM medic group.

References;

1. Heegard W, Hidlebrand=D D, Spear D, Chason K, Nelson B, Ho J. "Prehospital Ultrasound by Paramedics; Results of Field Trial". Academic Emergency Medicine, vol 17, #6, pp.624-630, 2010.
2. Walcker F, Weinlich M, Conrad G, et al. "Prehospital Ultrasound Imaging Improves Management of Abdominal Trauma". Br J Surg. 2006; 93:238-42.
3. Heegard W, Plummer D, Dries D, et al. "Ultrasound for the Air Medical Clinician". Air Med J. 2004; 23:20-3.
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SECTION 4 – AGENCY PROTOCOLS

Include agency protocols as an attachment for the proposed waiver as well as any potential protocols that may be impacted by this waiver request.



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SECTION 5 – TRAINING AND CQI

Education and Training

Education and training will be conducted by:

- Medical Director
- Training Center/Group previously identified
- Other (please list) Rocky Vista Medical University College of Osteopathic Medicine

Describe the proposed training to include, but not limited to:

- Curricula
- Didactic, skills, clinical requirements
- Competency evaluations
- Reference materials

Our proposal is for the pilot program is have the Advanced Resource Medics (ARM) from the South Metro Fire Rescue Authority attend an ultrasonography class similar to that presented at the Rocky Vista University College of Osteopathic Medicine (RVUCM). The anticipated course curriculum would be a single day course with the first half of the day devoted to the didactic curriculum and the second half of the day devoted to written multiple choice exam and then review of 25 case studies (half on models/ live EMS colleagues and the remaining half in the actual clinical environment). The didactic portion would be similar to the training format described by Heegaard, et al (1) in the Hennepin County EMS, Minneapolis, MN program in June 2010;

- | | | |
|---|-------------------------------|------------|
| • | Physics and image orientation | 60 minutes |
| • | Lung Exam | 60 minutes |
| • | Case Reviews | 30 minutes |
| • | Cardiac Exam | 40 minutes |
| • | Case Reviews | 30 minutes |

The initial training will occur on site with the Rocky Vista University College of Osteopathic Medicine (RVUCM) Physician staff instructors (Dr. David Ross DO, FACEP and 4th year RVUCOM ultrasound “student scholars“ whom are very well versed in ultrasound) led by Dr. John Kendall, MD from the University of Colorado School of Medicine and Denver Health Medical Center and Dr. Amanda Toney, MD, Director of Pediatric Emergency Ultrasound and Assistant Professor at Denver Health Medical Center.

In order to enhance the paramedic's sonography skills live subjects for ultrasound examination will used during the initial training phase. Currently we are requiring 25 uses of the ultrasound in a clinical environment with 100% physician over-read confirmation. The over-read confirmation will be performed by ultrasound fellowship trained physician. Following the successful completion of these 25 ultrasound examinations, the paramedic will be "cleared" to employ this procedure skill in the field. A test of skills retention will be performed at the 3 month post training mark.



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The initial phase of the project is to train the ARM paramedics to help determining the overall feasibility of the use of sonography. The next phase of the project would be to expand the group of trained paramedics by putting another group of experienced paramedics through the "Ultrasound Academy" using the identical training as the initial group. This next group of paramedics would then be stationed centrally in the South Metro Fire Rescue Authority response district at Station 44. This would keep the group of trained paramedics small and manageable while affording them the opportunity to respond to a larger group of varied patients where prehospital sonography may be of benefit.

Primary Instructor Credentials

(Not required if training is completed by Medical Director)

Name: Riccio, John Credentials: MD

Name: Credentials:

Name: Credentials:

(Include a resume and/or curriculum vitae for each instructor's teaching and clinical expertise in the area related specific to this waiver)

Quality Assurance/Improvement Methodology

May include, but not limited to:

- Audit criteria
- Percentage of audit
- Frequency of review
- Acceptable criteria
- Remediation process
- Termination criteria

Every occurrence of ultrasound examination will be submitted to, and audited by, the South Metro Fire Rescue Authority's Medical Director and Centura Health-South Denver Group Prehospital Services within 1 business day. Each occurrence will be assessed for proper utilization in terms of protocol adherence, indications for use of sonography, image quality, accurate reading, proper protocol referenced if treatment indicated and proper treatment chosen, and scene time interval. Physician over-read will be initially accomplished by ultrasound trained fellow physicians along with additional Medical Director oversight via over-reads will also be performed. Complications will be looked for but are not expected to be frequent in this non-invasive procedure. Any deficiency in evaluation of the sonography examination identified during review shall be immediately addressed by the Medical Director with any remediation deemed necessary carried out by the Medical Director with the assistance of the Continuing Education Coordinator and other personnel. Should a review of the study metrics indicate that scene times are increasing or that image quality, image interpretation



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accuracy, or selection of applicable treatment protocols are at unacceptable limits, the study will be discontinued.



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SECTION 6 – DATA COLLECTION

This section is required for renewals and transfers only

Include, as an attachment, data that has been collected during the waiver period.



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SECTION 7 – MEDICAL DIRECTOR ATTESTATION

Medical Director Attestation:

As Medical Director requesting this waiver, I have personally reviewed this waiver, and agree to abide by all data submission requests and other requirements as set for the by the Colorado Department of Public Health and Environment pertaining to this waiver. Failure to comply may result in immediate termination of this and all other waivers under my Medical Direction. I understand that failure to provide adequate supervision may result in notification made to the Colorado Medical Board.

John C. Riccio
Printed name

April 1, 2017
Date

Signature (insert as jpeg or bmp)