PUBLIC ACCESS DEFIBRILLATION

PROGRAM GUIDE AND APPLICATION PACKET

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PUBLIC ACCESS DEFIBRILLATION (PAD) PROVIDER RULES AND REGULATIONS

I. PURPOSE

a. To provide for system-wide public access defibrillation standards, review and oversight by the Emergency Medical Services (EMS) Section of the Kansas City, Missouri (KCMO) Health Department.

b. To provide structure to programs implementing automatic external defibrillators for use by lay persons treating victims of cardiac arrest.

c. To provide for integration of public access defibrillation (PAD) programs with the established emergency medical services system.

d. To provide a mechanism for PAD Quality Improvement activities across the Kansas City, Missouri EMS System.

II. AUTHORITY

a. Missouri Revised Statutes, Chapter 190, Section 190.092.

b. Chapter 34, Article XIV, Code of Ordinances of Kansas City, Missouri.

c. KCMO EMS Section Rules and Regulations.

   i. The Director of Health of Kansas City, Missouri is responsible for assuring that programs comply with the requirements of all applicable state, city, and local statutes and ordinances.

III. DEFINITIONS

a. Authorized Individual means any person, not otherwise licensed or certified to use the automatic external defibrillator (AED), who has met the training standards specified in this policy, and is authorized to use the AED by the medical director and program manager.

b. Automatic External Defibrillator or “AED” means an external defibrillator capable of cardiac rhythm analysis that will charge and, with operator action, deliver a shock after electronically detecting that a “shockable rhythm” is present.

c. Medical Director means a physician, licensed in the U.S., who develops, implements, and maintains the medical control provisions specified in this policy and authorizes individuals to operate an AED. Sample forms, training records, and protocols are included with this package.

d. Public Access Defibrillation or "PAD" refers to the utilization of AEDs by layperson rescuers to treat victims of cardiac arrest in public or private venues.

e. PAD Site refers to the agency, organization or company that sponsors a PAD program and allows placement of an AED on their premises.

IV. PROGRAM REQUIREMENTS

a. Any organization wishing to authorize an individual(s) to operate an AED on its premises in the City of Kansas City, Missouri shall apply to and be approved by the Kansas City, Missouri EMS Section.

   i. After submission of appropriate documentation, the PAD Site will be given an approval identification tag that will be attached to each AED.

   ii. The approval will remain in effect for a period of two years. The Kansas City, Missouri EMS Section will contact the PAD Site prior to the expiration date and the PAD Site will complete a re-approval process that ensures program requirements are current.

   iii. The PAD Site will notify the Kansas City, Missouri EMS Section of any changes (i.e., Medical Director, Program Manager, AED) that occur prior to the re-approval process.

b. Staff:

   i. Medical Director:

      1. The medical director must be a licensed physician. This individual is responsible for assuring the quality, integrity and legal compliance of the PAD program.

ii. Program Manager:

1. A program manager may be appointed by the medical director to oversee the administration of the PAD program.

c. A memorandum of agreement must be accomplished between the medical director and the organization wishing to establish the PAD program.

d. Program Plan:

i. A written description of the PAD program that should include but is not limited to, authorization of personnel, written protocols and case-by-case reviews.

e. Training:

i. A mechanism for the training and testing of the authorized individual(s) in the use of an AED.

1. This may be accomplished by an affiliation with an appropriate training entity. (Contact the EMS Section at (816) 513-6262 for a list of training organizations.)

ii. A list shall be maintained of individuals that have been trained and authorized by the medical director to use the AED.

iii. All training must meet or exceed the standards of the Heartsaver AED Course set forth by the American Heart Association or equivalent.

iv. The training standards prescribed by this section shall not apply to licensed, certified or other prehospital emergency medical care personnel as defined by Missouri Revised Statutes (Chapter 190), Chapter 34, Article XIV, Code of Ordinances of Kansas City, Missouri, and KCMO EMS Section Rules and Regulations.

f. Quality Assurance:

i. A quality assurance mechanism that will ensure the continued competency of the authorized individual(s) to include periodic training and skill proficiency demonstrations monitored by either the prescribing physician or his/her designee.

ii. Initial, refresher, and periodic training of all individuals authorized to operate the AED.

iii. A plan for utilizing the AED, including written protocols.

iv. A method to record and review each incident of an AED use.

g. AED Equipment and Maintenance Specifications:

i. All automatic external defibrillators utilized under this policy shall meet minimum standards set forth by of the Food and Drug Administration. (Contact the EMS Section at (816) 513-6262 for a current list of AED Vendors.) Consult with your medical director prior to purchasing any device.

ii. All defibrillators shall be maintained and regularly tested according to the operation and maintenance guidelines set forth by the manufacturer.

iii. Every AED shall be checked for readiness after each use and at least once every 30 days.

h. Documentation

i. Certain documents should be kept on file and should be made available to the EMS Section for review upon request. Documents should include (but are not limited to):

1. PAD Program Application (Attachment 1)
2. PAD Program "Memorandum of Agreement" (Attachment 2)
3. AED Protocol (Attachment 3)
4. AED Algorithm (Attachment 4)
5. Report of CPR or AED Use (Attachment 5)
6. AED Operator Training Record (Attachment 6)
7. AED Safety Inspection Record (Attachment 7)
8. Attachments 2 – 7 are "samples". A PAD program is not required to use these specific documents. The Medical Director and/or Program Manager may develop documents as applicable to their own program. Locally developed documents must meet or exceed the sample documents.

These documents are for illustration and example only, and do not constitute any offer or acceptance to provide legal advice to any PAD Program or person. Legal questions about documents involved in establishing a PAD Program, such as the Memorandum of Agreement between the Program and its Medical Director and other reports and records should be addressed to the Program's counsel.

9. AED Equipment and Maintenance Issues:
    a. Any manufacturer-recommended maintenance on the AED.
    b. Any repairs performed on the AED.
    c. Required safety inspections done on the AED.
    d. Any FDA medical products reporting in the event of an AED malfunction. (Please call the EMS Section at (816) 513-6262 or visit the FDA website at www.fda.gov/medwatch/report/consumer/consumer.htm

Attachment 1

PAD Program Application

Medical Director Information:

Name:		**License #:**	
Address:			
City:		**State:**	**Zip:**
Pager #:	**Work #:**	**Fax #:**	**E-Mail Address:**

PAD Program Site Information:

Facility Name:		**Facility Phone #:**	
Facility Address:			
City:		**State:**	**Zip:**
Program Manager:			
Pager #:	**Work #:**	**Fax #:**	**E-Mail Address:**
Number of Employees:		**Hours of Operation:**	
AED Brand & Model:		**AED Serial #:**	
Unusual Hazards at this facility:			

Training Organization Information: (if applicable)

Name:
Address:
Point of Contact:
Phone #:
Fax #:

Signing and submitting this application represents that you have read, understand, and will comply with the requirements of Missouri Revised Statutes, Chapter 190, Section 190.092, Chapter 34, Article XIV, Code of Ordinances of Kansas City, Missouri, and KCMO EMS Section Rules and Regulations. Your signature also represents that all information on this application is true and correct. Return this completed application to: Kansas City Health Department, Attn: Emergency Medical Services Section, 2400 Troost Avenue, Kansas City, MO 64108

Medical Director Signature: _____ Date: _____

Program Manager Signature: _____ Date: _____

Attachment 2
Public Access Defibrillation Program
Memorandum of Agreement

This agreement is made and entered into on _____

And is between _____,
Hereinafter known as “the MEDICAL DIRECTOR”;

And _____, hereinafter known as “the AGENCY”.

The purpose of this agreement is to establish a program for the utilization of defibrillation procedures by the authorized individual(s) employed by the AGENCY who will function under the supervision of the MEDICAL DIRECTOR. An agreement is required by Chapter 34, Article XIV, Code of Ordinances of Kansas City, Missouri.

THEREFORE, THE PARTIES NOW MUTUALLY AGREE AS FOLLOWS:

The MEDICAL DIRECTOR agrees;

1. To assume responsibility for all medical aspects of the program and to ensure, in cooperation with the program manager, that all administrative requirements are accomplished.

2. To conduct defibrillation training programs that meet or exceed the standards of the Heartsaver AED Course set forth by the American Heart Association or equivalent.

3. To establish a process that provides authorization-to-practice for individuals appropriately trained in the use of defibrillation equipment.

4. To establish a quality assurance program that reviews all uses of the defibrillation equipment and which provides for ongoing education and the regular evaluation of skill competency necessary to maintain authorization-to-practice.

5. To assist the AGENCY in establishing a plan to promote awareness, employee education, and provide a heart safe environment.

The AGENCY agrees;

1. To maintain with the MEDICAL DIRECTOR, an up to date roster of all individuals employed by the AGENCY who are authorized-to-practice.

2. To participate in all quality assurance procedures established by the MEDICAL DIRECTOR including case reviews and skill competency evaluations.

3. To utilize and abide by written protocols for the use of defibrillation equipment.

4. To establish policies for regular inspection and preventative maintenance of all defibrillation equipment and batteries.

5. To utilize only that equipment which is approved by the MEDICAL DIRECTOR.

6. To assist the AGENCY in establishing a plan to promote awareness, employee education, and provide a heart safe environment.

7. The PAD Program Manager of the City of Kansas City, Missouri, will be notified by the terminating party that the agreement will be terminated. This notification will be made at least 45 days prior to the date of termination.

It is AGREED TO BY ALL PARTIES that any party may terminate this memorandum of agreement with sixty (60) days written notice.

MEDICAL DIRECTOR;

_____
Print name

_____ _____
Signature Date

AGENCY;

_____
Print name

_____ _____
Signature Date

Attachment 3

Facility AED Protocol

Indications

- Patient with no signs of circulation and no breathing (signs of circulation include: normal breathing, coughing, moving or a pulse is present)
- This may occur in the setting of “sudden cardiac death”, electrocution, drowning, lightening strike, etc.

Contraindications

- Children under age 1 (estimate based on information available to individual operating the AED).
- Patient is breathing, responsive, speaking, or making intentional movements.

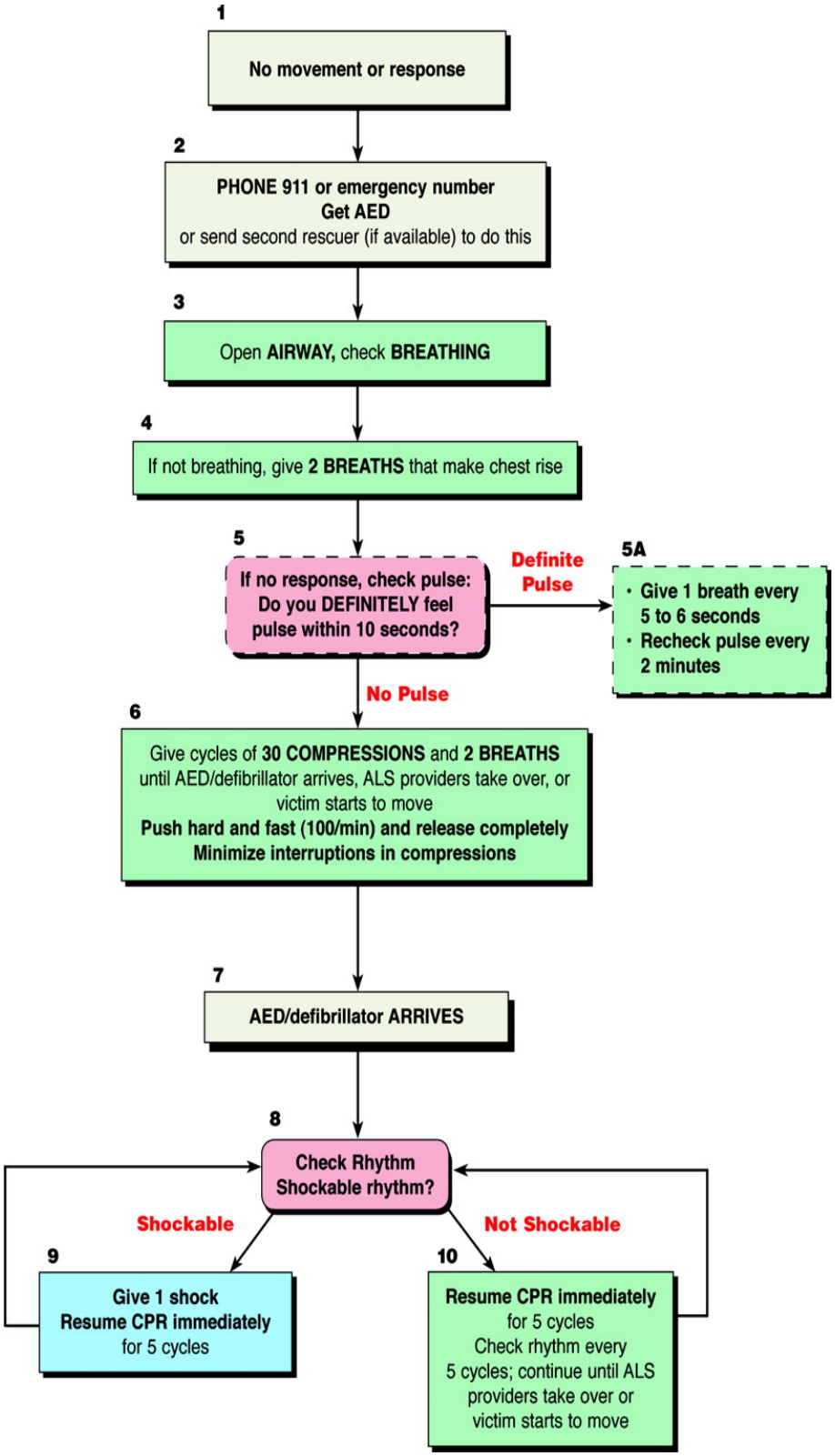
Potential Adverse Effects/Complications

- Burns to the skin.
- Electrical shock hazard if not used correctly.

Precautions/Critical Concepts

- Wet conditions – make sure the patient and environment are dry.
- Metal surfaces – make sure the patient is not touching any metal surfaces (e.g., tables, chairs, machinery, etc).
- Do not touch the patient while the AED is analyzing, charging, or shocking the patient.
- Ensure the patient is “clear” (no one is touching the patient) when the shock is delivered.
- Never defibrillate while moving the patient.
- Location of the AED(s) should provide optimal accessibility and allow for an ideal response time of less than 3 minutes. Upon placement of the AED, consider the following:
    - No obstacles are in the way of reaching the AED.
    - Avoid locked doors preventing quick access to the AED.
    - Areas of the facility with large numbers of high-risk individuals.
    - Length of time and distance to access the AED.
    - The AED is placed in a location clearly visible to the authorized operators.

Attachment 4



Attachment 5

Report of CPR or AED use to the EMS Section

Mandatory Data Elements
Name of PAD program:
Name of AED operator:
Place of occurrence: (specific location)
Date: (date of incident)
Time of incident:
Patient's name: (if able to determine)
Patient's age: (approximate if unable to determine)
Patient's sex:
Times: (approximate time if unable to determine)
Patient collapsed:
9-1-1 called:
CPR initiated:
AED attached:
Shock delivered: (if applicable)
Total number of defibrillation shocks:
Was there any return of spontaneous signs of circulation (pulse)?
Was there any return of spontaneous breathing?
Optional Data Elements
Circumstances of cardiac arrest
Was cause of arrest determined?
Any patient history?
Patient's allergies?
Patient's medications?
EMS OFFICE USE ONLY
Medical Director/Program Manager submitting report:
Date report received at EMS Section:
Patient prehospital outcome:
Patient disposition:

Provide a copy within 72 hours to:

PAD Program Manager
Medical Director
KCMO EMS Section

Attachment 6

AED OPERATOR TRAINING RECORD

Please complete and maintain the following information for each individual authorized to operate the AED(s) at your PAD site.

Name:	
Title:	
Age:	
Location where individual completed training:	
Date completed training:	**Initials:**
Date of refresher training:	
Date of refresher training:	
Date of refresher training:	
Date of refresher training:	

Signature of Operator:

_____

Date: _____

Signature of PAD Program Manager:

_____

Date: _____

Attachment 7

AED Daily / Monthly Safety Inspection Record for:

Year _____

Date: (Monthly)	Inspector Initials:	Carrying Case Intact:	Battery charged:	Additional equipment:

***Please complete a separate record for each AED**

Attachment 8

Missouri Revised Statutes

Chapter 190
Emergency Services
Section *190.092*

August 28, 2002

Defibrillators, use authorized when, conditions, notice--good faith immunity from civil liability, when.

190.092. 1. A person or entity who acquires an automated external defibrillator shall ensure that:

(1) Expected defibrillator users receive training by the American Red Cross or American Heart Association in cardiopulmonary resuscitation and the use of automated external defibrillators, or an equivalent nationally recognized course in defibrillator use and cardiopulmonary resuscitation;

(2) The defibrillator is maintained and tested according to the manufacturer's operational guidelines;

(3) Any person who renders emergency care or treatment on a person in cardiac arrest by using an automated external defibrillator activates the emergency medical services system as soon as possible; and

(4) Any person or entity that owns an automated external defibrillator that is for use outside of a health care facility shall have a physician review and approve the clinical protocol for the use of the defibrillator, review and advise regarding the training and skill maintenance of the intended users of the defibrillator and assure proper review of all situations when the defibrillator is used to render emergency care.

2. Any person or entity who acquires an automated external defibrillator shall notify the emergency communications district or the ambulance dispatch center of the primary provider of emergency medical services where the automated external defibrillator is to be located.

3. Any person who has had appropriate training, including a course in cardiopulmonary resuscitation, has demonstrated a proficiency in the use of an automated external defibrillator, and who gratuitously and in good faith renders emergency care when medically appropriate by use of or provision of an automated external defibrillator, without objection of the injured victim or victims thereof, shall not be held liable for any civil damages as a result of such care or treatment, where the person acts as an ordinarily reasonable, prudent person, or with regard to a health care professional, including the licensed physician who reviews and approves the clinical protocol, as a reasonably prudent and careful health care provider would have acted, under the

same or similar circumstances. Nothing in this section shall affect any claims brought pursuant to chapter 537 or 538, RSMo.

Attachment 9

Chapter 34, Article XIV, Code of Ordinances of Kansas City, Missouri

Article XIV. Public Access Defibrillation Program

Sec 34-551. Title.

This article shall be known and may be cited as the "Public Access Defibrillation Program Code."

Sec. 34-552. Purpose.

It is the purpose of this code to create the public access defibrillation program and establish guidelines for use, training, and data collection, as well as requirements and procedures for implementing and using AEDs within this program.

Sec. 34-553. Definitions.

(a) *Authorized* user means any person who has met the training standards of this code, and is authorized to use the AED by the medical director and program manager.

(b) *Automated external defibrillator* or *AED* means an external defibrillator capable of cardiac rhythm analysis that will charge and, with or without further operator action, deliver a shock after electronically detecting that a “shockable rhythm” is present.

(c) *Director* means the director of health or persons to whom the director has delegated duties imposed by this code.

(d) *Health care facility* means a hospital, nursing home, physician's office or other fixed location at which medical and health care services are performed.

(e) *Medical director* means a physician authorized by the State of Missouri to permit individuals to operate an AED and who develops, implements and maintains the medical control provisions of this code and the regulations promulgated pursuant to this code.

(f) *Program manager* means a person who works with the medical director to oversee the administration of the PAD program.

(g) *Public Access Defibrillation* or *PAD* means the utilization of AEDs by rescuers to treat victims of cardiac arrest in public or private places, including first aid providers at public events not associated with the prehospital emergency medical services provider for the City, staff of nursing homes not otherwise exempt by this code, and similar activities.

(h) *PAD site* means the agency, business, organization, or other entity that sponsors a PAD program and allows placement of an AED on its premises.

Sec. 34-554. Exceptions.

The following entities or persons are exempt from the provisions of this code:

(a) *Hospitals.* Hospitals licensed by the State of Missouri.

(b) *Physicians.* Persons licensed by the state of Missouri as a physician pursuant to Chapter 334, RSMo.

(c) *Nurses.* Persons licensed by the state of Missouri as a nurse pursuant to Chapter 335, RSMo.

(d) *City EMS system.* Persons licensed by the City and working for the ambulance system contractor or persons working for the City's fire department if those persons have been approved for use of an AED by the City's medical director for prehospital emergency medical services.

(e) *Mutual Aid Providers.* Persons working for state licensed ambulance services, governmental fire departments or other EMS agencies that are operating legally in conjunction with the City's EMS system.

Sec. 34-555. Use of AEDs.

No person shall begin a public access defibrillation program after March 31, 2003, unless the program is certified by the director of health. Public access defibrillation programs operating on March 31, 2003, may operate for one year from that date without being certified by the director of health. Thereafter, all public access defibrillation programs shall be certified by the director of health.

Sec. 34-556. Director of Health duties.

(a) *Adopt regulations.* The director shall adopt regulations necessary to implement a public access defibrillation program within the authorization of this code, Missouri law and regulations, and current medical standards for the use of AEDs and prompt treatment of people suffering cardiac arrest.

(b) *Register medical directors*. The director shall maintain a list of registered medical directors who shall be licensed physicians.

(c) *Authorized* programs. The director shall maintain a list of authorized programs reflecting their intent to operate a PAD program pursuant to this code.

(d) *Public access defibrillation programs*. The director shall maintain a list of PAD program sites.

(e) *Audit*. The director shall have the right to audit any use of an AED. The director may review maintenance and repair records, training records, medical director agreements, reports of cardiopulmonary resuscitation or AED use, and any other records necessary to determine compliance with the terms of the PAD program. An audit, or quality assurance review, may include gathering clinical data and information from the person who used the AED, and from the AED itself.

(f) *Delegation*. The director of health may delegate duties to appropriate personnel, including the medical director of the prehospital emergency medical services system working through the director's office, the Emergency Physicians Advisory Board, or other persons or entities determined by the director to be qualified to oversee the operations of PAD programs.

Sec. 34-557. PAD program duties.

(a) *Training.* Any person acquiring an AED will authorize the use of the AED only by persons who have received training by the American Heart Association or American Red Cross, or an equivalent nationally recognized course approved by the director including the identification of cardiac arrest, administration of cardiopulmonary resuscitation, and the use of AEDs. However, this is not meant to imply that a PAD program can not place an AED in a public setting (the so called "fire extinguisher" mode) where an untrained citizen could use it in an emergency until an authorized user or a member of the City's EMS system arrived.

(b) *Maintenance and testing.* Any person acquiring an AED will maintain and test the unit according to the manufacturer's operational guidelines. Records of maintenance and testing will be made available to the director upon request.

(c) *Notification of use of the AED.* Any person who renders emergency care or treatment on a person by using an AED must notify the EMS system through proper use of the 9-1-1 system or other means to seek prehospital emergency medical services.

(c) *Medical control.* Any person acquiring an AED for use outside a health care facility shall have an authorized physician provide the medical protocol for the use of the device. Protocols will be made available to the director upon request.

(d) *Cooperation with the director.* A person acquiring an AED and the user of an AED will fully cooperate with the director in any audit or other quality assurance review, including the retrieval of clinical data from the device itself by the director.

(f) *List of authorized users.* A PAD program will maintain a list of the persons participating in the program reflecting the persons' training and qualifications. This list will subject to audit by the director.

Sec. 34-558. Certification of participants in a PAD program.

(a) *Director of health duties.* The director of health may establish criteria for the certification of AED programs.

(b) *Periodic certification.* The director of health is authorized to require recertification of the program at intervals established by regulation.

Sec. 34-559. Violations.

It is unlawful to:

(a) Fail to cooperate with the director in the investigation, audit or other review of the use of an AED; or

(b) Fail to make the AED available to the director for the recovery of data; or

(c) Fail to properly maintain and test an AED made available for use.

(d) Fail to relinquish control of patient care to appropriately licensed members of the Kansas City prehospital emergency medical services system on their arrival.

Sec. 34-560. Severability.

Should any portion of this code be held invalid or unenforceable, the remaining provisions of this code shall remain in effect.