GENERAL SERVICES ADMINISTRATION

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SAFETY STATION PROGRAM GUIDELINES IN FEDERAL FACILITIES

TO: Heads of Federal agencies

SUBJECT: Safety Station Program Guidelines in Federal Facilities

AUTHORITY: These guidelines were prepared, in part, in response to directives contained in the House Report and the Joint Explanatory Statement. The House Report stated that:

> Sudden cardiac arrest is a leading cause of death for Americans, and early intervention and timely use of an [AED] significantly improves the chances of survival. In 2001, Congress required the creation of a [PAD] program that included voluntary guidelines for deployment of AEDs in Federal buildings. Furthermore in 2009, GSA and the [[HHS] issued a FMR] bulletin on Guidelines for Public Access Defibrillation Programs in Federal facilities. The Committee directs GSA, in coordination with HHS as the lead agency with health policy expertise, to update the 2009 FMR bulletin to reflect advances in AED technologies and to examine whether AEDs should be required in Federally owned buildings under the custody and control of GSA.

The Joint Explanatory Statement further noted that:

> In addition to the House report directive on [AEDs] in public buildings, the

> agreement directs GSA to work with the [HHS] to examine whether AEDs should be required in federally owned buildings under the custody and control of GSA. GSA and HHS shall issue an updated FMR bulletin no later than 1 year after enactment of this Act.

In addition to the House Report and the Joint Explanatory Statement, section 247 of the Public Health Service Act (42 U.S.C. § 238p) directs the Secretary of HHS to establish and publish guidelines with respect to placing AED devices in Federal buildings. The Secretary of HHS also has authority to provide health information under Section 1704 of the Public Health Service Act (42 U.S.C. § 300u-3).

Additional statutory basis for the establishment of a federal safety station program can be found in 5 U.S.C. § 7901, which authorizes the head of each Federal agency to establish, within the limits of appropriations available, a health service program to promote and maintain the physical and mental fitness of employees under that agency's jurisdiction. Further support is also found in 40 U.S.C. § 301 note (specifically, the 1950 Reorganization Plan No. 18), which transferred to GSA all functions with respect to the operation of general purpose office buildings owned by the Federal Government and of office buildings or parts thereof acquired by lease, and 40 U.S.C. § 121(c), which authorizes the Administrator of GSA to prescribe regulations that the Administrator considers necessary to carry out the Administrator's functions with respect to such property.

The head of each Federal agency is also directed to establish and maintain an effective and comprehensive occupational safety and health program (see 29 C.F.R. § 1960.1).

For Federal agencies in space under the jurisdiction, custody or control of GSA, the

Designated Official under the facility's Occupant Emergency Plan (as defined in 41 C.F.R. § 102–71.20) is responsible for oversight of the facility's safety station program. As provided in 41 C.F.R. § 102–71.20, the Designated Official is the highest ranking official of the primary occupant agency of a Federal facility, or, alternatively, a designee selected by mutual agreement of occupant agency officials. Regulations outlining the establishment, coordination and implementation of a comprehensive Occupant Emergency Plan are set forth in 41 C.F.R. §§ 102-74.230 through 102-74.260, entitled "Occupancy Emergency Program." For these purposes, the definition of "emergency" includes medical emergencies (see 41 C.F.R. § 102-71.20). Safety station programs should evolve based on the best available science to assure the most efficient use of resources and the best outcomes possible.

PURPOSE: The primary purpose of these guidelines is to provide a general framework for establishing a design process for safety station programs in Federal facilities. A secondary purpose is to familiarize Federal agencies with the three modular bystander-empowered components and the essential elements associated with each component of such a program. The design of a safety station program for any Federal facility will be unique and depends on many factors, including the population demographics of the facility, the size and location of the facility and the surrounding area. The design process and key elements of the safety station program described in these guidelines are intended to provide a foundation upon which individually tailored programs are established and maintained. Additional information on guidance on safety station programs can be found at https://www.hhs.gov/about/agencies/asa/psc/physical-security-emergency-management/safety-stations/index.html.

It is important to note that the safety station program is voluntary and not mandatory for Federal facilities. The costs and expenses to establish and operate a safety station program are

the responsibility of the Federal agency or agencies sponsoring the program and not GSA or HHS, except to the extent GSA or HHS, or both, are sponsoring a program in a facility where they are occupant agencies.

BACKGROUND: HHS and the GSA were jointly directed by Congress to update the 2009 Bulletin to reflect advances in AED technologies and to examine whether AEDs should be required in Federally owned buildings under the jurisdiction, custody, and control of GSA. HHS and GSA have collaborated to update the 2009 Bulletin on PAD programs to incorporate more all-encompassing safety station program guidelines that incorporate two modular bystander-empowered components, specifically, (a) opioid reversal agents (such as naloxone) and (b) hemorrhagic control (such as STB), where either one or both can accompany an AED.

Concept of Safety Stations: Where the previous version of this bulletin recommended establishing an AED program in Federal facilities, this version expands the concept of an AED program further by introducing the "safety station." The idea of the safety station is to enable anyone located within a Federal facility to access the necessary tools quickly and easily to respond to an emergency situation. Anywhere that an AED was previously located can and should be converted to a safety station.

The concept of the safety station is designed to be a modular one – and the three major components can be added or left off based upon a facility or agency's specific needs. Each safety station is recommended to consist of, at a minimum, an AED and supporting equipment as described in further detail in this bulletin. It is highly recommended that each station also includes either a bystander-empowered opioid reversal agent or hemorrhagic control component, or both, as described in further detail in this bulletin. While these components are the recommended minimum, it is also recommended that anyone creating a safety station in a facility

consider keeping the station uncluttered, with clear visibility and access to the equipment and supplies. Placing too much equipment or multiple sets of directions in a location can have the effect of overwhelming the lay person or employee-rescuer and it can become a hindrance. Each safety station must be clearly marked and visible.

In addition to establishing safety stations in Federal facilities, it is highly recommended that Federal agencies create or update existing First Aid/cardiopulmonary resuscitation (CPR)/AED training programs to include training for employees on opioid reversal agents and hemorrhagic control. Program management is discussed in further detail in a later section of this bulletin.

- AED - According to the American Red Cross, sudden cardiac arrest is a leading cause of death in the United States. The only way to restore a regular heart rhythm during cardiac arrest is with an AED. For every minute that defibrillation is delayed, the odds of survival are decreased by 10%. Having a publicly accessible AED is critical in a sudden cardiac arrest (SCA) situation.

  "Public access" to AEDs does not mean that any member of the public who witnesses an event should be able to use an AED. "Public access" refers to the accessibility of the device itself. While AEDs are reasonably uncomplicated to use, the AED is recommended to be used by persons who have received proper training and education from a nationally recognized training institution or association. The AED in a safety station is recommended, at a minimum, to include the AED itself and unexpired defibrillation pads that are connected and prepared. The AED should be inspected regularly to ensure operation and sufficient battery or charge for use. It is also recommended that the AED have audio instructions and pictures to assist the lay person

in possible life-saving use.

- Opioid Reversal Agent - Although FDA-approved opioid analgesic medications have been found safe and effective to alleviate moderate to severe pain, misuse of such opioid drugs or use of illicit opioids may lead to further misuse, addiction, or overdose, or any combination of the foregoing, for some individuals. An opioid overdose is a life-threatening situation by rapidly slowing one's breathing and heart rate, which can lead to death. Immediate intervention is imperative. CDC data show a rise in the number of opioid overdose deaths since 1999, with 80,411 reported opioid overdose deaths in the United States in 2021. Opioid overdoses are often preventable with an opioid reversal agent (such as naloxone) nearby, as the opioid reversal agent can quickly restore breathing to a person whose breathing has slowed or stopped. These agents act rapidly and can revive a person from an overdose within minutes.

  Opioid reversal agents such as naloxone have no effect on a person who does not have opioids in their system and should be administered to anyone who shows signs of an opioid overdose or when an opioid overdose is suspected. In 2020, the Morbidity and Mortality Weekly Report reported that 37% of overdose deaths had someone else present. Adding an opioid reversal agent to a safety station provides another opportunity for access and availability. More information on the recommendation can be found at https://www.cdc.gov/mmwr/volumes/69/wr/mm6935a1.htm.

  Further information for responding to an opioid overdose can be found in the Substance Abuse and Mental Health Administration's Opioid Overdose Prevention Toolkit, which can be found at https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.

It is also recommended that all safety stations contain - a within expiry date U.S. Food and Drug Administration (FDA)-approved opioid reversal nasal spray product. These products are easy to use by bystanders and those with or without formal training. Further information is available from the National Institutes of Health's Naloxone drug facts page at https://nida.nih.gov/publications/drugfacts/naloxone.

- Hemorrhagic Control - The American College of Surgeons reports that our Nation's threat from intentional mass casualty events remains elevated. More information on the American College of Surgeon's report can be found at: https://bulletin.facs.org/2015/07/the-hartford-consensus-iii-implementation-of-bleeding-control/. The report noted that enhancing public resilience to all such potential hazards has been identified as a priority for domestic and emergency preparedness. Over the past several years, advances in technology have provided several innovative opportunities to prevent unnecessary disability and death. One of many notable advances in this technology is hemorrhagic control. Uncontrolled bleeding represents the number one cause of preventable death, after injury, responsible for up to 40% of trauma mortality; 33% –56% of these deaths occur in the prehospital period. More information on uncontrolled bleeding statistics can be found at https://pubmed.ncbi.nlm.nih.gov/36311340/. Immediate post-injury care requires training in the recognition and treatment of a bleeding emergency, as well as access to bleeding control equipment. Thus, the report concludes that "opportunities exist in the form of interventions that should be performed by bystanders known as immediate responders and professional first responders, such as law enforcement officers, emergency medical technicians, paramedics, and firefighters, at the scene of the

incident."

Military experience has demonstrated that immediate control of prehospital bleeding can decrease morbidity and mortality. After the Sandy Hook Elementary School mass shooting in 2012, the American College of Surgeons convened a panel of experts to address the issue of providing immediate lifesaving care after injury. Known as the Hartford Consensus, these best-practice recommendations called to educate and equip the public with techniques of appropriate control of life-threatening bleeding. This resulted in the consensus that individuals, without direction, should act immediately and respond to assist professional responders during an intentional or unintentional disaster. This also resulted in the agreement that a program was necessary to educate and train the public to ensure they knew how to protect themselves and act immediately and independently during an emergency. Soon thereafter, the American College of Surgeons' National Safety Council expanded the concept into a national initiative called Stop the Bleed® (STB).

The STB program advances bleeding control principles by informing, educating and empowering the public. It enables the public to serve as immediate responders in communities, using the skills necessary to recognize and control excessive bleeding. The program strategically collaborates with multiple organizations and establishes close ties to local, state and federal officials to promote support for the program at all levels of government and industry and works towards ensuring that equipment is readily available in communities through advocacy and community efforts. In addition, training the public to be immediate responders enables those individuals to initiate the trauma chain of survival, beginning the critical interventions necessary to move the victim through the

emergency care continuum. The trauma chain of survival is five interdependent links that recognize the increased chance of survival for the trauma victim if the chain is not broken. The chain begins with the immediate responder and moves the victim through the trauma system, ending with the trauma center and trauma surgeon providing the necessary life-saving care. The STB program provides the education and the equipment.

ESTABLISHING A SAFETY STATION PROGRAM IN FEDERAL FACILITIES: Before establishing a safety station program in a Federal facility, each occupant agency should enlist the assistance of not only the personnel at that location, but also local training, medical and emergency response resources. These partnerships are fundamental to any successful safety station program. In some instances, a facility may be large enough to have training, medical and emergency response resources integral to the Federal operations. For the most part, though, this will be the exception rather than the rule, but the same principles apply. The more closely the safety station program is connected to such resources and the more visibility and support given to the program by the facility leadership, the more the program will be effective and successful.

Each safety station program should include the following major elements:

- Support of the program by each of the facility's occupant agencies.
- Consideration of individual employee and union interests in accordance with collective bargaining agreements.
- An acquisition strategy and plan to achieve the safety station program objectives.
- Training and retraining personnel in safety station bystander-empowered components.
- Obtaining medical direction and medical oversight from nationally recognized institutions or agencies.
- Understanding the legal aspects of establishing and operating the program.

- Development and regular review of the safety station program and standard operating procedures.
- Development of an emergency response plan and protocols, including a notification system to activate responders.
- For Federal agencies in multi-occupant facilities, clarity on the decision-making processes, authority and funding for the safety station program.
- Integration with facility security and Emergency Management Systems (EMS).
- Maintaining hardware and support equipment on a regular basis and after each use (Note: safety station components are not building equipment and, as such, are not inventoried or maintained by GSA or property management personnel).
- Educating all employees regarding the existence and activation of the safety station program.
- Tailor program to address health disparities to help make a difference where a disadvantaged social group has persistently experienced social disadvantage or discrimination and systematically experience worse health or greater health risks than more advantaged social groups. More information on addressing health disparities can be found at https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.118.004989.
- Development of quality assurance and data/information management plans.
- Development of measurable performance criteria, documentation of performance, and periodic program review.
- Review of new technologies.

It is important to emphasize that safety station programs are not isolated "one-time events." Safety station programs should be reviewed on a regular basis and improved, where possible.

Additionally, after every incident involving the use of the safety station, a thorough post-event review of system performance should be undertaken.

A key element in assuring that the safety station program will be clearly understood and will function well is the development of standard operating procedures for the major components of the program. Standard operating procedures, as well as the program as a whole, should be periodically revisited and revised, where appropriate.

Program Management: A lead organization/agency should be identified as a coordinating entity for an agency- or facility-based safety station program. System-wide or community safety station programs may need to include the designation of a medical director. Medical directors are typically responsible for reviewing, approving and overseeing medical programs. Additional state and local rules, regulations and protocols (such as state and local EMS agency involvement) should also be considered.

Routine checks of equipment contents and integrity, as well as systems of accountability, asset tracking and resupply mechanisms should be included in program design. After use of a kit, the remaining contents should be decontaminated (if necessary), inventoried and resupplied.

- AED
    - Medical Direction – Although AEDs are approved to be used by laypersons in emergency situations with no formal training and certifications, it is recommended that AEDs are to be used under the advice and consent of a physician and only by individuals with the proper training and certification. Medical oversight is recommended as an essential component of PAD programs. This oversight can be provided either by a facility's own physician, through

existing federal resources or by a contracting physician, in accordance with applicable federal laws. It is best to seek medical input from the very beginning of the design of the program. A physician should be involved as a consultant in all aspects of the program. Medical and physician oversight does not mean that a physician is required to be present to manage the PAD program on a day-to-day basis. However, it is prudent for facility leadership to develop management of and oversight protocols for lay program overseers so that quality is consistently maintained. Additionally, a central role for the physician is conducting assessment of the PAD system's performance after the use of an AED, including review of the AED data and the electrocardiograph tracing of the victim.

  - Maintenance - An AED maintenance schedule is imperative to keeping the device and its accessories properly functioning. Maintenance requirements vary from one AED model to another. Therefore, it is important to understand fully how to properly maintain AEDs at a facility. In addition, the maintenance requirements can also inform the type of AED that should be acquired when conducting market research.

- Opioid Reversal Agent - Safety stations containing opioid reversal agents should be clearly marked to indicate their presence, and facility staff should be trained to recognize the safety station cabinets containing the opioid reversal agent so they can quickly respond in the event of an overdose. More information on implementation of opioid overdose reverse agent stations at the U.S. Department of Veterans Affairs can be found at

https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/508/VAAEDNaloxoneToolkit_508.pdf.

  - Medical Direction - There are several opioid reversal agents available without a prescription for which use does not require medical direction.
  - Maintenance - An intranasal opioid reversal agent should be kept in the box or storage container until ready for use. It should be protected from light and stored at room temperature (59 - 77°F or 15 - 25°C). Note the expiration date and replace when it has expired.

- Hemorrhagic Control
  - Medical Direction - Hemorrhagic control kits contain components that are to be used by individuals with the proper training and certification. While programmatically they do not require medical oversight by a physician, it is best to seek medical input from the very beginning of the design of the program. It is prudent for facility leadership to develop management and oversight protocols for providing care so that quality is consistently maintained.
  - Maintenance - Although the shelf life of most supplies and equipment in these kits is undated, hemostatic dressings have shelf lives that require tracking for expiration date and replacement. Further, kits should be routinely checked on a regular, established basis to monitor for unrecognized use, tampering and degradation due to environmental exposure.

Training: Even where large facilities have self-contained emergency medical services systems, it is still advisable to devise a training program for the lay responder and rescuers (LRR). The greater the number of well-trained LRRs that are available, the more effective a safety station

program will be. Overall effectiveness will be improved as the number of personnel who are fully trained and willing to respond increases. As a general matter, in facilities where there are enough personnel to permit in-house training programs, a routine training schedule should be established. An additional benefit of in-house training is that training in groups that correspond closely with work groups tends to build a better sense of team and responsibility than would individual, separate training.

Nationally recognized training organizations, such as the American Heart Association, the American Red Cross and the National Safety Council, provide materials and guidance through a variety of courses that include combined CPR, AED, opioid overdose reversal, and hemorrhagic control training. These programs provide comprehensive materials for the training of people that are targeted toward providing information and training necessary to assess the status of a victim competently and administer care.

Although universal precautions are taught in CPR, AED and hemorrhagic control classes, additional bloodborne pathogen training is highly recommended for immediate responders. Agencies should organize their responses around a team approach using either identified first responders or existing emergency response resources, such as building security. All training programs should include a component that describes and explains the facility-specific program. All retraining or refresher programs should, likewise, include this component to assure that first responders are aware of the most current information regarding their specific emergency care program.

Training is not a one-time event. Leadership should seek to maintain and improve the first responders' skills and abilities. Formal training should be conducted at the frequency as recommended by the nationally recognized training organization used by the agency, but at least

every two years. Mock drills and refresher sessions engage teams in periodic "scenario" practice sessions to maintain skills and rehearse protocols. Mock drills and refresher practice sessions will be important to maintain current knowledge and a reasonable comfort level in responding to and providing emergency care. Mock drills are recommended on an annual basis and the mock drill results should be reviewed by the program's medical director. The frequency of refresher sessions will vary from facility to facility and should be established in consultation with the physician providing medical oversight.

- AED - Today's AEDs are relatively inexpensive and usable by persons with limited training. The advantage of a structured safety station program is that it provides a better trained individual, increased accessibility and, as a result, increases the potential to reduce response times and markedly increases the probability of survival and full recovery.

  It is imperative that members of the workplace be trained in the rapid and positive intervention reflected in the American Heart Association's Chain of Survival concept.

- Opioid Reversal Agent - Intranasal opioid reversal agents are designed to be easily used by an untrained bystander. However, training employees in the signs of an opioid overdose and in the use of an opioid reversal agent eases concerns that employees may have in administering an opioid reversal agent on an individual. More information on opioid overdose training from a law enforcement perspective can be found at https://pubmed.ncbi.nlm.nih.gov/27715714/.

  The American Red Cross offers an online course "First Aid for Opioid Overdoses," which can be found at https://www.redcross.org/take-a-

class/opioidoverdose; however, many local, state and nonprofit organizations also offer training in opioid reversal agents at no cost.

The CDC's NIOSH fact sheet "Using Naloxone to Reverse Opioid Overdose in the Workplace: Information for Employers and Workers" can assist workplace decision makers in developing their own training. The fact sheet can be found at https://www.cdc.gov/niosh/docs/2019-101/default.html.

- Hemorrhagic Control - Some hemorrhagic control programs may require additional training if there are children in the facility, *e.g.*, a daycare facility.

Acquisition Vehicles: There are several Federal acquisition vehicles that may be used in the development of a safety station in a Federal facility or for the program management aspect of maintaining a safety station.

- GSA, through its Global Supply ordering site, which can be found at https://www.gsaglobalsupply.gsa.gov/, and through GSA Advantage, which can be found at https://www.gsaadvantage.gov/, offers both AED devices and STB kits. Each site contains a search functionality to find the specific product for a safety station.
- The U.S. Department of Veterans Affairs maintains a Federal Supply Schedule, which can be found at https://www.va.gov/opal/nac/fss/schedules.asp, and a Contract Catalog Search Tool, which can be found at https://www.vendorportal.ecms.va.gov/nac/, to find contracts for items for a safety station.
- The Defense Logistics Agency maintains a Medical Electronic Catalog (ECAT) program as found on the following website: https://www.medical.dla.mil/Portal/ECAT/EquipmentECAT.aspx, which is an e-commerce acquisition program that offers 1.1 million medical items from 215 vendors

across the United States. ECAT specializes in providing niche medical items not normally provided by medical prime vendors (large national distributors). ECAT services can service over 7,000 potential federally funded customers worldwide, delivering quality medical products at fair and reasonable prices.

- As of late 2023, FDA has approved several nonprescription forms of naloxone nasal spray. See e.g., https://www.fda.gov/news-events/press-announcements/fda-approves-second-over-counter-naloxone-nasal-spray-product.

  Naloxone can be purchased through federal contracted vendors, such as the HHS Medical Supply Fulfillment and Support, which can be found at https://www.hhs.gov/about/agencies/asa/psc/supply-chain-management/medical-supply-fulfillment-support/index.html, and the previously mentioned U.S. Department of Veterans Affairs Federal Supply Schedule. State health departments also may supply so long as the opioid reversal agent is stored in the state of acquisition.

- Hemorrhagic control kits, such as the STB kits, are available from many commercial suppliers and through the GSA Federal Supply Schedule, which can be found at https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule. Each kit will typically contain a tourniquet, an instructional booklet or pamphlet, assorted dressings, some form of hemostatic gauze or agent, a chest seal, trauma shears, an emergency survival blanket, and a miniature permanent marker. Recommended kit contents are available from the American College of Surgeons through the STB website or from other sources readily available to the public.

- Additional information on guidance on acquisition vehicles on safety station programs can be found at https://www.hhs.gov/about/agencies/asa/psc/physical-security-

emergency-management/safety-stations/index.html.

DESIGNING A SAFETY STATION PROGRAM:

Personal Protective Equipment:

Body Substance Isolation (BSI) reduces the transmission of infectious materials from moist body substance regardless of the presumed victim's infectious status. BSI was developed by nurses and colleagues in large hospitals and more information can be found at https://www.sciencedirect.com/science/article/pii/S0197457287801143.

Personal Protective Equipment (PPE), such as disposable nitrile gloves, and other first aid equipment, such as a responder rescue mask, a face shield or a bag value mask (for use in rescue breathing or CPR), is recommended to be procured and stored beside other safety station supplies for responder safety.

Acquisition:

- AED - The actual selection and procurement of AEDs should be one of the last steps in the design of a facility's PAD program and should be done under the guidance and written authorization of the PAD program's supervising physician. The protocol for AED usage that is developed as part of a facility's PAD program is an integral part of the physician's medical oversight and serves as the authorizing document for AED use. Protocols should be reassessed periodically in accordance with a regular schedule of reviews as determined in consultation with the PAD's supervising physician. A current protocol that takes into consideration both new treatment recommendations and any changes in the FDA-approved labeling of the AED should be integrated into the PAD training and education and retraining programs.

Essentially, the protocols that are signed by the supervising physician set the medical standards and criteria for the operation of the PAD program and all of its components. Systems operated within the scope of these signed protocols are considered to be under a physician's supervision, whether or not the physician is physically present in the facility. As noted in this guidance, PAD programs should be reviewed on a regular basis (after each activation and on a regular basis) with changes made, as needed, under the direction of the supervising physician. Revised protocols should be in accordance with current *American Heart Association Guidelines for CPR and Emergency Cardiovascular Care*.

- Equipment
  - Existing - Check to see if existing AED and AED accessories are FDA-approved and listed on the following website: https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds#accessories. If the AED or the AED accessory, or both, is not listed on the referenced FDA site, then contact the manufacturer of the AED or the AED accessory, or both, as applicable, for more information about the device.

    Continue to keep the AED available for use, even if it is not FDA-approved, until you obtain an FDA-approved AED, given the importance of these devices in emergency situations. Be aware that if the AED is not FDA-approved, compatible AED accessories may no longer be available to support the AED.
  - Selecting New - To ensure the quality and reliability of AEDs, the FDA requires manufacturers to obtain premarket approval for all AEDs and

AED accessories. More information on FDA's premarket approval process is listed on the following website: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.

- Once an AED and AED accessory is on the market, the FDA proactively monitors their safety and reliability by reviewing a variety of information that manufacturers are required to submit to FDA, including manufacturing and design changes, medical device adverse event reports, and other types of information FDA may require as a condition of approval. When a company initiates a corrective or removal action, FDA posts information about the action on the Medical Device Recall Database at the following website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

- Opioid Reversal Agent
  - Equipment - It is recommended to stock a minimum of two doses of an intranasal opioid reversal agent per safety station because, in some cases, one dose may be inadequate to reverse an overdose. More information on the recommendation can be found at https://www.cdc.gov/stopoverdose/naloxone/index.html#:~:text=There%20are%20two%20forms%20of,prefilled%20nasal%20spray%20and%20injectable. The size, layout and accessibility of the workplace may require placement of doses in multiple locations. Consider the time needed to replace supplies when

determining the number of doses to stock. Some workplaces may choose to stock more than two doses per safety station depending on a risk assessment.

- Hemorrhagic Control - Bleeding control programs should include and select standardized kits that include the following:
    - Wound Management Supplies. Bleeding control gauze dressings, including hemostatic gauze, when possible, should be included. Dressings can be placed over the wound while providing manual pressure or packed directly into bleeding wounds. Hemostatic dressings contain compounds that promote the clotting of blood and facilitate timely control of bleeding. Compression-type pressure dressings may also be included as adjunctive treatments to allow for pressure to be maintained.
    - Chest Seal. Used for the treatment of penetrating injuries to the chest.
    - Tourniquet. The most consistently effective tourniquets are commercially manufactured. Tourniquets should be aligned with the Tactical Combat Casualty Care-recommended devices and adjuncts for tourniquets.
    - Support Equipment. Latex-free medical protective gloves, Just-in-Time instructions for lay people and trauma shears.

Safety Station Placement

- Location - While there is no single "formula" to determine the appropriate number, location and access system for a safety station, there are several major elements that should be considered. However, all considerations are based upon (1) an optimal response time of three minutes or less and (2) an assessment of the level of risk in a facility’s environment. Factors that should be considered include:

- Response Time: The optimal response time is three minutes or less. This interval begins from the moment a person is identified as needing emergency care to when the safety station component is deployed and is at the side of the victim. With an SCA incident, the survival rates decrease by 7 to 10 percent for every minute that defibrillation is delayed. Information on SCA survival rates can be found at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2600120/#:~:text=In%20a%20study%20of%20148,survival%20rate%20was%20only%2049%25. For an opioid overdose incident, a victim's breathing and heart rate is slowed down or stopped, which can result in a number of health complications and eventually death if not immediately treated. More information on the effects of opioid overdoses can be found at https://aspe.hhs.gov/reports/non-fatal-opioid-overdose-associated-health-outcomes-final-summary-report-0#results. For a hemorrhagic incident, a 1-minute delay with implementing hemorrhagic control translates to a 2 percent increase in 30-day mortality and a 1 1/2 percent increase in 24-hour mortality. More information on hemorrhagic control survival rates can be found at https://pubmed.ncbi.nlm.nih.gov/36728324/. Therefore, it is recommended that Federal agencies train as many employees as possible on the use of safety stations.
- Demographics of the Facility's Workforce: Leadership should examine the composition of the resident workforce. Since the likelihood of an event occurring increases with gender, ethnicity and age, special consideration should be given to the gender, ethnicity, and age profile of the workforce.

- Visitors: Facilities (including Federal areas, such as wilderness areas and national parks) that host large numbers of visitors are more likely to experience an event, and an appraisal of the demographics of visitors should be included in an assessment.
- Specialty Areas: Facilities where strenuous work is conducted are more likely to experience an event. Additionally, specialty areas within facilities, such as exercise and workout rooms, should be considered to have a higher risk of an event than areas where there is minimal physical activity.
- Physical Layout of Facility: Response time should be calculated based upon how long it will take an LRR with a safety station bystander-empowered component walking at a rapid pace to reach a victim. Large facilities and buildings with unusual designs, elevators, campuses with several separate buildings, and physical impediments all present unique challenges to LRRs. In some larger facilities, it may be necessary to incorporate the use of properly equipped "golf cart"-style conveyances to accommodate time and distance conditions.
- Physical Placement of Safety Stations: Facilities that have large open areas present unique challenges.
- GSA should be notified of any alterations necessary to accommodate the placement of safety stations in facilities under the jurisdiction, custody or control of GSA.

- Placement - There are several elements that contribute to the proper placement of AEDs. The major elements are:

- An easily accessible position (*e.g.*, placed at a height so shorter individuals can reach and remove the device, unobstructed access).
- A secure location that prevents or minimizes the potential for tampering, theft or misuse, and precludes access by unauthorized users. Facilities should take additional steps to assure that the safety station has not been stolen or improperly removed.
- A location that is well marked, publicized and known among trained staff. Periodic "tours" of locations are recommended.
- A nearby telephone that can be used to call backup, security, EMS, or 911 to be sure that additional help is dispatched.
- Protocols should clearly address procedures for activating local EMS personnel. These protocols should include notification of EMS personnel of the quantity, brands and locations of AEDs within the facility. This information will enhance dispatch and the EMS responder protocol, enabling proper planning and scene management once EMS personnel arrive at the victim's side. Equipment stored in a manner in which the removal of the AED automatically notifies security, EMS or a central control center is ideal.
- Where automatic notification of the opening of a safety station or removal of an AED or component from a cabinet is not implemented, emphasis should be placed on notification procedures and equipment placement in close proximity to a telephone.

Environmental Conditions: Follow manufacturer instructions for storing AEDs, opioid reversal agents and hemorrhagic control kits. Safety station components should be kept in the box or storage container until ready for use.

Waste Management

- PPE - Nitrile gloves should be replaced every five years to be sure they do not tear or break when needed.
- AED - AEDs typically last, on average, 5 to 15 years depending on how the AED was stored and how well it was properly maintained. AED and AED accessories should be disposed of or recycled according to federal, state and local regulations. AEDs contain electronic parts and are classified electronic waste when the item is scrapped at the end of its service life. It is recommended to dispose of all end-of-life AEDs through an accredited electronics recycling facility. More information on electronics recyclers can be found on the following website: https://www.epa.gov/smm-electronics/certified-electronics-recyclers. In the event an electronics recycler is not available in your area, then contact your local or state government to determine if the AED and AED accessories waste falls under an electronic waste classification.
    - AED Batteries
        - Battery Disposal - AED batteries can either be rechargeable (lithium-ion) or non-rechargeable (lithium metal) and, when spent, are classified as universal waste in accordance with the U.S. Environmental Protection Agency (EPA). For frequently asked questions on lithium batteries, visit the following website: https://www.epa.gov/recycle/frequent-questions-lithium-ion-batteries.

        - Re-Celled Replacement Batteries - An environmentally preferred and economic alternative to original equipment manufacturer, non-rechargeable, AED batteries are new re-celled replacement AED batteries. Re-celled replacement AED batteries provide the same performance and life as the original battery and must undergo FDA premarket approval process.

- Opioid Reversal Agent - Opioid reversal agents must be replaced before the expiration date indicated on its packaging and after it has been used. There also may be an occasion where the offending agent is still present and will need to be disposed, as well. There are multiple ways to dispose of unusable reversal agents or the offending agent, or both.
    - Permanent Collection Site - The U.S. Drug Enforcement Administration (DEA) has authorized permanent collection sites to safely and securely gather and dispose of unused or expired medications. Authorized collection sites may be retail, hospital or clinic pharmacies, and law enforcement facilities. These collection sites may offer on-site medicine drop-off boxes, mail back programs or other in-home disposal methods to assist in safely disposing of unused or expired medicines. An authorized drug collection site may be located through the following website: https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1 or by calling the DEA Diversion Control Division Registration Call Center at 1-800-882-9539, for more information about these collection sites.
    - Periodic Take Back Events - The DEA hosts National Prescription Take Back events every October and April. During these events, temporary drug collection

sites are set up in communities nationwide for safe disposal of prescription drugs. More information on National Prescription Drug Take Back days can be found at the following website: https://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html.

Local law enforcement agencies may also sponsor take back events in your community. Contact your local waste management authorities to learn more about events in your area.

- Drug Deactivation Systems - Disposable drug deactivation pouches offer a convenient method to deactivate and dispose of residual or expired medication in an effective and safe manner. The nonprofit addiction recovery advocacy group The SAFE Project shows drug deactivations system options on https://www.safeproject.us/disposal/.
- Mail Back Systems - Expired or used opioid reversal agents or offending agents can be placed in a secure mailer and mailed to a destruction company. Reach out to local medical waste companies for more information on this method.

- Hemorrhagic Control - Hemostatic dressings have shelf lives that require tracking for expiration date and should be replaced when they expire.

Maintaining a Safety Station Program: Re-evaluate your program periodically and assess for new risks. Plan for maintaining equipment and restocking expended supplies, expired supplies (including replacement of expired opioid reversal agents), other consumable first aid supplies, PPE, and malfunctioned accessories.

Environmental Preferable Purchasing: EPA issues the Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing to help Federal purchasers identify and

purchase environmentally preferable products and services. It is recommended, where applicable and feasible, to procure healthcare products and services per EPA's guidance to minimize the safety station program's environmental footprint at a Federal facility.

LEGAL ISSUES: Any safety station program should be reviewed by agency legal counsel so that the program, as designed, follows all applicable federal laws. Safety station programs establish procedures for dealing with emergency medical situations that present an appreciable risk of serious bodily injury and death regardless of the degree of care exercised by those involved in responding to the situation. These situations are often the subject of regulation by various authorities. The risk of liability for failing to comport with applicable regulations, and for acts or omissions that result in harm, are important and ever-present concerns that should be addressed in the safety station program. Though federally owned facilities generally are not subject to state and local authority, federal law can incorporate or adopt specific state and local authorities or otherwise make them applicable to federal facilities.

One of the most important legal concerns with any safety station program will be the potential liability of those who respond to the emergency situation, including, potentially, Federal employees. The following legal principles should be considered in developing a safety station program.

Generally, the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2401(b) and 2671–80 (FTCA), immunizes Federal employees acting within the scope of their employment from personal liability for most tortious conduct. FTCA coverage is determined on a case-by-case basis. Whether a particular person is covered by the FTCA depends upon an analysis of whether the person is considered an "employee," which is determined by federal law, and whether that

person was acting within the scope of employment, which is determined by the Department of Justice, subject to judicial review, applying state law.

The FTCA provides that liability is determined according to the law of the place where the wrongful or negligent act or omission occurred. Under the FTCA, the Federal Government is not liable for the wrongful acts of any person who is not a "Federal employee" as defined in 28 U.S.C. § 2671. The United States is subject to liability for the negligence of an independent contractor only if it can be shown that the government had authority to control the detailed physical performance and exercised substantial supervision over the day-to-day operations of the contractor. Thus, a safety station program should consider placing responsibility for responding to emergency medical situations on a contractor over whom the Federal Government does not exercise day-to-day control. The safety station program should, however, include criteria to assure that the contractor has the requisite expertise, training and resources.

Many states have enacted legislation to provide some degree of immunity to lay individuals who provide assistance to people in distress. The laws are called "Good Samaritan" laws. Since these laws vary state-by-state, management of the federal facilities should seek legal counsel for the law applicable to the state where the federal facilities are located.

- AED – Section 248 of the Public Health Service Act (42 U.S.C. § 238q) provides additional protection from civil liability for AED use. This statute provides persons who use or attempt to use an AED, and persons who acquire an AED, immunity from civil liability for harms resulting from the use or attempted use of the AED, subject to a number of important exceptions. The statute provides default immunity only. The federal immunity supersedes state law only to the extent that a state has no statute or regulation that provides users or acquirers with immunity for civil liability arising from

the use of an AED in an emergency situation. The statute explicitly states that its provisions are not intended to waive any protections from liability for Federal officers and employees provided in the FTCA or the Federal Employees Liability Reform and Tort Compensation Act of 1988, commonly known as the Westfall Act. 28 U.S.C. § 2679(d). The primary purpose of the Westfall Act is "to protect federal employees from personal liability for common law torts committed within the scope of their employment, while providing persons injured by the common law torts of federal employees with an appropriate remedy against the United States." In essence, the Westfall Act provides for the substitution of the United States where the Attorney General's designee certifies that a federal employee committed the acts at issue while acting within the scope of their employment. Nothing in these guidelines or in any PAD program established pursuant to these guidelines should be read as creating a duty for Federal employees or contractors not otherwise existing under applicable state or Federal law to provide assistance to persons in medical distress.

- Opioid Reversal Agent – To increase availability to first responders and the general public, many states have enacted laws to protect lay people who administer naloxone in good faith in an emergency from civil or criminal liability, or both. The Legislative Analysis and Public Policy Association has drafted a summary of the laws in all 50 states and the U.S. territories. This summary can be accessed at https://legislativeanalysis.org/wp-content/uploads/2023/02/Naloxone-Access-Summary-of-State-Laws.pdf.

MENTAL HEALTH: Responding to medical trauma can leave lasting effects on an individual's overall health and well-being. Mental health includes emotional, psychological and

social well-being. It affects how an individual thinks, feels and acts. It also helps determine how an individual handles stress, relates to others and makes healthy choices.

The plan for the safety station program should include access to immediate care by a professional healthcare provider, referral for follow-up care and ongoing support for any worker who is a victim of sudden cardiac arrest, opioid overdose or hemorrhagic bleeding. In addition, the plan should include emergency assistance and support (*i.e.*, Employee Assistance Program and mental health services) for lay staff responders and bystanders, if necessary. Additional information on guidance on mental health resources concerning safety station programs can be found at https://www.hhs.gov/about/agencies/asa/psc/physical-security-emergency-management/safety-stations/index.html.