NORTHWEST COMMUNITY EMERGENCY MEDICAL SERVICES SYSTEM

EST 1972

Audit action strategies/evolving Federal landscape Compliance and accountability: Controlled substances

Policies: **C6: EMS Controlled Substance Program**

New controlled substance logs: ambulances & NT

Controlled substance waste documentation at hospital

D3: Drug/pharmacologic management

SOPs: Respiratory illness – Protecting HC workers

Health alerts: Coronavirus; synthetic opiate; & sodium nitrite

End of year data: trends to watch

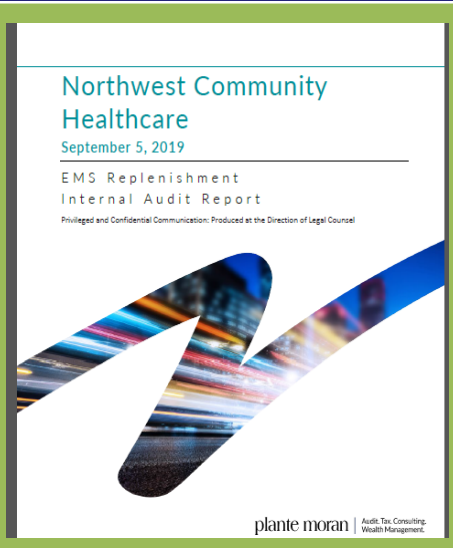
Objectives:

After completing the class and reading the referenced documents, each participant will do the following with a degree of accuracy that meets or exceeds the standards established for their scope of practice without critical error:

***Cognitive*:** Explain the major provisions and rationales of the SOPs, procedures, and policies presented in this micro-learning format so they are applied appropriately to patient situations and documented accurately.

Psychomotor: Accurately maintain inventories and chain of custody for all controlled substances and non-controlled EMS supplies and pharmacologics. Accurately complete CS inspections and logs, and document waste using the new Image Trend tool.

Affective: Advocate for policy compliance, risk mitigation, and appropriately executed procedures in the safe and timely delivery of EMS care.



Goal: All EMS practitioners are well-informed about updates to policies, procedures, and care and translate this knowledge into clinical practice.

Questions and comments welcome. Direct to:

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February 2020 CE – Learning modules & points of discussion

A. Audit report: Objective; scope, conclusions; issues requiring action plans; resulting policy changes
    1. C6: EMS Controlled Substance Program
    2. New controlled substance logs: ambulances & NT
    3. Controlled substance waste documentation at hospital
    4. D3: Drug/pharmacologic management
B. IDPH Health alerts:
    1. Response to 2019 Novel Coronavirus (CDC)
    2. Potent synthetic opioid – Isotonitazene in Midwest
    3. Sodium nitrite exposure; use of methylene blue
C. Protecting Healthcare workers
D. EMS System end of year data (2019) and trends to watch
E. Legal Q&A if time allows

Audit Objective

To assess whether EMS replenishment processes and controls in place are in accordance with policies, procedures, and regulations.

Audit Scope

- Evaluated EMS restocking practices for adherence with approved drug, supply, and equipment list.
- Validated that meds, supplies, and equipment were adequately stored, tracked, and recorded and access was restricted to approved personnel.
- Reviewed CS practices related to EMS restock, return of damaged or expired products, diversion, and waste disposal for adherence with regulations and EMS P&P.
- Confirmed P&P were documented & consistently followed.

CONCLUSIONS

Improve EMS replenishment process including disposals, replenishment from non-EMS Pyxis machines, agency log-ins, reconciling medications and supplies, safeguards to EMS Pyxis room, and bin maintenance.

Receiving medications in the case of shortages, CS logs, and med diversion monitoring should be formally documented.

List of issues for action plans

- Inconsistent CS wastes and returns
- EMS replenishment from ED supplies
- Inconsistently documented/reviewed CS logs
- Lack of documentation of med diversion monitoring
- Undocumented replenishment of EMS meds from pharmacy dept.
- Lack of inventorying of EMS Non-CS meds
- Lack of safeguards around EMS supplies
- Lack of proper disposal of EMS NC meds & supplies
- EMS Pyxis maintenance

LEGAL and REGULATORY REQUIREMENTS: The procurement, prescribing, administration, and transfer of CS are highly regulated by federal and state laws and regulations, as well as compliance standards (Joint Commission and Centers for Medicare and Medicaid Services). The possession and administration of controlled substances is governed by the U.S. Department of Justice Drug Enforcement Administration. This policy establishes the EMS standards for management of Controlled Substances (CS) by NWC EMSS agencies, hospitals, and personnel in accordance with Federal DEA Rules and Regulations. The Federal Rules are found in the Code of Federal Regulations (Title 21 CFR, Part 1300-1399), the Controlled Substance Act, and Public Law 115–83 Nov. 17, 2017 131 STAT. 1267 Protecting Patient Access to Emergency Medications Act of 2017 (PPAEMA). See the DEA website. www.deadiversion.usdoj.gov

DEA REGISTRATION: The DEA requires that each site that stores or dispenses CS be registered. Before 2017, an EMS agency was authorized to administer CS under the DEA registration of the EMS medical director overseeing the agency's patient care. Language added by PPAEMA now allows EMS agencies to receive their own DEA registration to administer controlled substances.

DEFINITIONS

CONTROLLED SUBSTANCES: Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. See Table 1. CS, as approved for EMS administration in the NWC EMSS, include fentanyl, morphine, ketamine, midazolam, diazepam, and others as approved by the EMS MD.

Use of Standing Orders: The PPAEMA allows EMS agencies to "*administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional*." To do so, the EMS agency must 1) be authorized to do so by state law and 2) have a standing order or verbal order from a medical director or an authorizing medical professional.

Id. § 823(j)(4); "**Medical director**" is defined as a physician registered with the DEA to administer controlled substances and who provides medical oversight to an EMS agency. See 21 U.S.C § 823(j)(13)(H) (2017).

"**Standing order**" is defined as "*a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances" to EMS patients.* See 21 U.S.C § 823(j)(13)(M) (2017).

"**Verbal order**" is defined as "an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional." See 21 U.S.C § 823(j)(13)(N) (2017).

I. POLICY

A. All drugs approved for distribution to EMS agencies and administration to EMS patients shall be procured, deployed, stored, inventoried, clinically administered, documented, restocked, and records kept in compliance with laws, rules, regulations, and policies and procedures that govern EMS drug oversight and administration.

B. EMS personnel licensed, credentialed, and authorized to access or handle CS are educated and competent in established policies, procedures, and regulatory requirements.

C. CS are stocked in as ready-to-use form as possible and in the lowest commercially available units frequently given to EMS patients. Inventory is routinely evaluated for opportunities to reduce the need to waste.

D. The System advocates for a collaborative and interdisciplinary approach to and accountability for CS diversion prevention and response within the System that supports a culture of safety for patients and healthcare workers.

E. Under no circumstances may any drug or pharmacologic deployed to an EMS agency be diverted for personal purposes or use by EMS personnel unless the recipient is logged as a patient and is being treated by appropriate EMS personnel and care is documented in the electronic medical records reporting system.

F. **EMS Agency Liability**. EMS agencies under the EMS MD's supervision, are liable for ensuring the proper use, maintenance, reporting, and security of CS used by the agency. Before the PPAEMA, liability regarding use of CS by an EMS agency was placed on the DEA-registered medical director or the hospital overseeing the agency.

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that--

1. *all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;*
2. *the recordkeeping requirements are met with respect to a registered location and each designated location of the agency;*
3. *the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with* the storage subsection*;* and
4. *the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted* (NWC EMS protocols and policies)*.*

II. PROCEDURES – Administrative requirements, oversight, accountability, operational flow

A. **PROCUREMENT:** Controlled substances will be issued by the assigned System hospital to each new EMS ALS vehicle as it is approved for operation within the NWC EMS System per the inventory levels listed on the Drug and Supply List for ambulances and EMS Policy M9: MedENGINES for Alternate response vehicles.

B. **DRUG ADMINISTRATION:** ALS EMS personnel may administer approved CS outside the physical presence of a medical director or authorizing medical professional in the course of providing EMS care in compliance with the NWC EMSS SOPs.

1. Label all CS drawn up into syringes, if not immediately administered, with the drug name and dose withdrawn, and the initials of the healthcare worker (HCW) who drew up the drug written on the label.
2. Keep syringes containing CS under the direct control of the person preparing the syringes until administration to the patient.
3. When sequential doses are required from a single syringe, document the doses given as separate entries in the ePCR. Each PCR shall be signed by 2 ALS personnel.
4. Note the amount wasted (if applicable) in the ePCR and at the hospital.

C. **STORAGE and SECURITY**

1. EMS agencies may store CS in the agency location registered with the DEA, unregistered locations, and in EMS vehicles (as defined below) used by the agency under circumstances that provide for security of the CS consistent with the requirements established by regulations of the Attorney General.
2. ***EMS vehicles may store controlled substances if they are***
   a. *situated at a registered or designated location of the agency; or*
   b. *in an emergency, the EMS vehicle used by the agency is:*
      (1) *traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or*

(2) *otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General* and NWC EMSS Policies and Procedures.

The United States Attorney General must be notified of all unregistered locations at least 30 days before the CS are initially delivered to those locations.

3. **Storage in DRUG BAGS:** ALS Agencies may store approved CS in a "drug bag". However, the container of CS must be stored separately from non-controlled substance drugs and be secured using a device such as a tamper detectable plastic tie lock. ALS personnel must be in control of the bag containing CS at all times when not secured in a locked location on the EMS vehicle or in the Agency Station as described below.

4. **Storage in EMS VEHICLES**: CS must be stored in a secure fashion in a "substantially constructed tamper resistant locked cabinet" with 24 hour/day accountability to prevent diversion or tampering. CS shall be stored with the ability to examine for tampering, expiration dates, and inventory counts. EMS Agencies are encouraged to consider, but are not mandated, to use technology such as the CyberLock Access Control System that records all openings of the locked cabinet and creates an audit report to confirm the person who has accessed the CS. See https://cyberlock.com. Access to EMS vehicles shall be limited. They shall be occupied or locked and keys removed whenever deployed outside of quarters. EMS quarters shall be locked or have secured limited access.

D. **Additional SECURITY controls**

1. In order to minimize the opportunities for theft or diversion of CS, EMS agencies have an obligation not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons.

2. **Access:** The EMS Agency/Registrant must limit access to CS to a minimum number of authorized employees.

   a. **Controlled substances may be accessed by ALS EMS personnel.** The Agency/Registrant may designate other individuals to access controlled substances but the designation must be in writing identifying the individuals granted access.

   b. All **access shall occur in the presence of two personnel** authorized by the Agency/registrant. All **access shall be recorded and witnessed**. (Daily Controlled Substance Log signatures; medication cross-check documented in ePCR).

   c. Individuals authorized by the Agency/Registrant can pick up and transport CS. Incidental contact by EMTs helping the ALS personnel carry equipment while on scene is allowed but the ALS practitioner must be in control of access to these medications at all times.

3. **Recommendation:** Although not specifically required by Federal law or regulation, the following additional security measures are recommended to enhance overall security: Change all CS container lock combinations or passcodes upon termination of any employee with knowledge of the combination(s), regardless of the reason for the termination.

4. **Out-of-Service:** EMS vehicles that are out-of-service (inoperable, not available for current operation, no crew available, not functional) shall have their CS removed, secured and accounted for per the Agency medication management plan. This does not apply to an ambulance that is OOS secondary to the crew having lunch, completing reports or other duties, which prevent temporary response to calls.

5. **CS on Non-EMS vehicles prohibited:** "Jump bags" (bags carried by personnel in their personal or Agency vehicles not listed in the Agency's EMS Plan with IDPH) shall only carry drugs or supplies that are sold over the counter. No CS may be stored in personal or Agency non-EMS vehicles or on personal property.

E. **MONITORING and SURVEILLANCE:**
Daily Accountability for CS Inspections, LOGS, and Record keeping:

The System will perform a variety of audit processes to identify inventory discrepancies and the possible diversion of CS.

1. The DEA has defined three basic requirements regarding CS records:
   a. Records should be readily retrievable.
   b. Records should be kept for two years.
   c. Records should be available for DEA inspection in an efficient and business-like manner and in a sequence that can be easily reviewed on site or back at DEA offices. Orderliness, legibility, and a format compatible with a copy machine are important.

2. EMS agencies must follow **record requirements** stated in the CS Act. These requirements include recording all CS that are received, administered, or otherwise disposed of and storing records in the locations where CS are received, administered, and discarded.
   Such records ``*(i) shall include records of deliveries of controlled substances between all locations of the agency; and ``(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of."*

3. Each Agency must maintain an **unbroken chain of custody** and internal controls as evidenced by a **fully completed Controlled Substance Log** for each EMS vehicle that carries controlled substances. The logs shall be maintained at each registered and designated location of the agency where the CS are stored.

4. **DAILY COUNTS:** At the start of every shift or transition of crew members (if more frequent than daily), all CS shall be visually examined using a double-count process whereby **two different licensed ALS practitioners** with NWC EMSS ALS privileges (preferably one from the off-going and one from the on-coming crew whenever possible) simultaneously inspect and count the drugs for comparison to required System inventories, last count numbers, evidence of tampering, and expiration dates. The double-count process is for the protection of the ALS practitioners, both to prevent diversion and to avoid culpability should there be a discrepancy in the count.

5. **CS LOG DOCUMENTATION:** The signatures (written or electronic on the PDF fillable form) of the two ALS practitioners completing the daily CS inspection/count, their legible EMS license numbers, as well as the numeric drug counts must be entered onto the Controlled Substance Log. Note and initial changes in EMS inventories during that shift.

6. **PROCESSING OF CONTROLLED SUBSTANCE LOGS**
   a. **PEMSC Review**: The PEMSC shall review all CS logs for completeness on a periodic basis (best practice model: weekly). At the end of the month, the PEMSC shall inspect the document for completeness, sign, and date their final review.
   b. **Missing information:** If documentation is incomplete or missing, the PEMSC shall notify the ALS personnel who are accountable for missing

counts/signatures to **append an explanation to the record** as to why an entry was missing. Under no circumstances are signatures to be added on the daily count lines at a later date to amend the record.

c. **Forward to assigned hospital EMSC/educator:** The PEMSC shall forward the log originals and all appended explanations to the agency's designated Hospital EMSC/Educator no later than the 4th week of the following month.

d. **Hospital EMSC/educator review:** The HEMSC/ed shall also review the form(s), verify completeness, and sign and date their review. If signatures or counts are omitted without reasonable appended explanation, an RFC shall be forwarded to the PEMSC and agency Chief/ EMS CEO or designee seeking an explanation and improved performance.

e. The original logs with appended explanations, PEMSC and HEMSC/ educator signatures and shall be **electronically archived** at the designated System hospital in accordance with DEA procedures (2 yrs).

7. **INCIDENT INVESTIGATION and REPORTING:**
Count discrepancies, theft, or loss of CS

ALS personnel shall notify the Provider EMSC, EMS MD, and EMS Administrative Director of all count discrepancies, suspected theft, or loss of any controlled substance immediately upon discovery of such discrepancy, loss or theft. Suspected thefts shall also be reported to local law enforcement agencies.

a. All reasonable avenues will be pursued to account for the missing drug(s). Discrepancies must be resolved within 24 hours of discovery. (Best practice model: within same shift.)

b. **Initiate an RFC:** If an agency experiences a count discrepancy due to loss, theft, or missing CS that cannot be immediately and acceptably explained and resolved, complete a Request for Clarification Form (RFC). The EMS Admin Director can assist the PEMSC in identifying elements that must be included in their internal investigation (e.g., signed statements from all EMS personnel accountable for the chain of custody before and after the drug(s) were missing) and other reporting requirements.

c. Federal regulation requires that registrants **notify the DEA** Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance **within one business day** of discovery of such loss or theft.

(1) The Agency shall complete and submit DEA Form 106, "Report of Theft or Loss of Controlled Substances". (21 C.F.R. § 1301.76(b). See https://apps.deadiversion.usdoj.gov/webforms/dtlLogin.jsp. The EMS MD may need to assist in filling out the report as a DEA # is required.

(2) DEA CS registrants are strongly encouraged to complete and submit the DEA Form 106 online. In addition to being more convenient, completing the form online results in fewer errors.

8. **Evidence of tampering:** If any CS appears to be tampered with or is not sterile and/or ready for patient administration, ALS personnel shall immediately bring the situation to the attention of their Provider EMSC. If the PEMSC is unavailable, they shall notify an EMS agency officer to immediately begin an internal investigation. Evidence of tampering must also be reported immediately to the EMS MD and EMS Administrative Director.

a. Immediately remove the CS with questionable tampering from vehicle inventories. Note the removal in the CS log.

b. Provide the drug in its original packaging to the PEMSC or agency supervisor who shall bring it to the agency's assigned System hospital pharmacy for assay, wasting, and restocking.

F. **DISCIPLINARY ACTION**: Prohibited behaviors such as a break in the chain of custody of controlled substances, lying or deceit about inventory checks/drug counts; falsification of EMS records, diversion of drugs for personal purposes or use; or two or more instances of an unexplained discrepancy during a practitioner's duty cycle is grounds for disciplinary action by the EMS Agency and/or EMS MD.

III. PROCEDURE AT SYSTEM HOSPITALS

A. All system hospitals must maintain inventory standards for CS in compliance with DEA and Joint Commission requirements and EMS best practice models.

B. **Restocking EMS Vehicles at Hospitals**. Following an emergency response, EMS agencies may receive CS from a hospital for purposes of restocking without completing CSA order forms provided the following are met:

1. **Exchange:** Empty CS drug containers are to be given to receiving hospital ED RNs for exchange with information relative to the patient who received the drug. Empty CS containers are discarded in limited-access waste containers that render the waste irretrievable and waste procedures comply with organizational procedures for waste management.

2. The **Agency/registrant** maintains a record of such receipt where the vehicle is primarily situated (NWC EMSS ePCR and Controlled Substance Logs). The EMS Agency/registrant is required to keep written documentation of this transaction for a period of (2) years.

3. The **hospital** maintains a record of providing CS to the agency: The hospital is required to keep written documentation of this transaction for a period of 2 years.

4. After receiving replacement CS inventory, **the following shall be verified by two ALS personnel before placing into and resecuring the EMS CS container:** Medication, correct concentration, amount; and expiration date. Ensure that counts are current and accurate against the CS Log.

C. **Wasting CS**: If the amount of a CS drug given is less than the prepackaged or prepared dose, the ALS practitioner shall bring in the remaining medication to be appropriately wasted in the presence of an ED nurse per the hospital's policy. CS shall be wasted as close to the time of arrival at the hospital as possible. Any amount of a CS that is wasted shall be witnessed by at least two authorized medical professionals (1 RN and 1 ALS practitioner) and recorded. The name and signature of the nurse witnessing the wastage must be documented in the ePCR and on hospital records per hospital policy. The DEA prefers to have a 3rd party witness when possible, but is not mandatory.

D. **Breakage and Spillage of CS**: Breakage does not constitute a "loss" of CS. When there is breakage, damage, spillage, or some other form of destruction, all recoverable controlled substance must be disposed of according to DEA requirements. **Bring all damaged or broken containers to your assigned System hospital** for disposal. If the breakage or spillage does not allow recovery of the drug, the Agency/registrant must document the circumstances of the breakage in the Controlled Substance log. Two individuals who witnessed the breakage must sign the log indicating what they witnessed.

E. **Returns of Expired CS Drugs**: Controlled substances that are expired or within 14 days of expiration or need to be removed from inventory for any reason cannot be wasted. The Agency/Registrant shall **return the drug to their assigned System hospital for disposal and replacement** in compliance with that hospital's exchange policy and procedure. The hospital will need to request permission from the DEA to dispose of any controlled substance. The hospital shall submit DEA Form 41 at least 14 days in advance of the proposed disposal. The preferred method of disposal is to use a reverse distributor (a DEA registered disposal firm.) Other methods need approval from the DEA District Office.

Table 1 **Schedules of controlled substances**

Schedule	Definitions	Examples
I	High abuse potential with no accepted medical use; medications within this schedule may not be prescribed, dispensed, or administered	Heroin, marijuana, ecstasy, gamma hydroxybutyric acid (GHB)
II	High abuse potential with severe psychological or physical dependence; however, these medications have an accepted medical use and may be prescribed, dispensed, or administered	Morphine, codeine, hydrocodone, hydromorphone, methadone, oxycodone, fentanyl, methylphenidate, pentobarbital
III	Intermediate abuse potential (ie, less than Schedule II but more than Schedule IV medications)	Hydrocodone/acetaminophen 5 mg/500 mg or 10 mg/650 mg; codeine in combination with acetaminophen, aspirin, or ibuprofen; anabolic steroids; ketamine
IV	Abuse potential less than Schedule II but more than Schedule V medications	Propoxyphene, butorphanol, pentazocine, alprazolam, clonazepam, diazepam, midazolam, phenobarbital, pemoline, sibutramine
V	Medications with the least potential for abuse among the controlled substances	*Robitussin AC*, *Phenergan* with codeine

References:

1. Controlled Substances Act of 1970, Pub.L. 91–513, Title II, 84 Stat. 1242.
2. Protecting Patient Access to Emergency Medications Act of 2017, Pub.L. 115-83, 131 Stat. 1267 (amending 21 U.S.C. § 823 (2017).
3. Opioids are used to manage pain in patients suffering from fractures, trauma, and other painful medical conditions. Benzodiazepines are used to stop potentially life-threatening seizures. See Patient Care, QI and General Safety Comm., National Emergency Medical Services Advisory Council, EMS Utilization of Controlled Substances (2017).

21 U.S.C § 823 (2016). The current list of controlled substances can be found on the DEA website or in 21 C.F.R. §1308.

https://www.congress.gov/115/plaws/publ83/PLAW-115publ83.pdf
https://www.cdc.gov/phlp/publications/topic/briefs/ema/index.html
https://www.ems.gov/pdf/Draft-EMS-Utilization-of-Controlled-Substances-011817.pdf

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Northwest Community EMS System

CONTROLLED SUBSTANCE (CS) LOG AMBULANCE - Rev. 1/1/20

EMS Agency:_____ Vehicle ID#_____Month/Year:_____

Instructions: This log must be signed daily by two different PMs (one off-going and one on-coming) AND initialed whenever the CS inventory is changed after visually inspecting drugs to confirm that they are present, intact, within exp. dates, and in required quantities**.** If any alternate drug is added due a shortage, note on the log (see example). If any drug is not present, the discrepancy must be reconciled immediately per System policy C6 Controlled Substances. Note the number present in that column. **Begin a new Log on the first day of each month**.

Date	Signatures	EMS license #	Fentanyl 100 mcg (3)	Morphine 10 mg (2)	Midazolam 10 mg (2)	Diazepam 10 mg (2)	Ketamine 500 mg	Change Initials
Ex	Off going *John Doe* Oncoming *Jane Smith*	060112032 060000046	3 / 0	0 / 2	2	0	1	JD / JS
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Northwest Community EMS System

CONTROLLED SUBSTANCE LOG AMBULANCE 1/1/20 Page 2

EMS Agency:_____ Vehicle ID#_____Month/Year:_____

Date	Signatures	EMS license #	Fentanyl 100 mcg (3)	Morphine 10 mg (2)	Midazolam 10 mg (2)	Diazepam 10 mg (2)	Ketamine 500 mg	Change Initials
16								
17								
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Instructions: **Return the completed Log to your PEMSC** who will review for QI purposes, sign, and forward to the assigned Hospital EMSC/educator by the 4th week of the following month to review, sign, and electronically archive for at least two years. The signer affirms that they have reviewed this Log for CQI purposes. If any signatures or counts were omitted, I have addressed the omissions with the involved personnel and have appended their explanations to this form.

Signature: Provider EMS Coordinator Date

Signature Hospital EMSC/educator Date

I. **POLICY**

A. The Northwest Community EMS System (NWC EMSS) is committed to the safe and secure stocking, storage, administration, documentation, disposal, replacement, and reporting of sentinel events relative to EMS drugs, pharmacologics, and medical supplies.

B. *The EMS Program Plan shall contain a list of all drugs and equipment required for each type of System vehicle and procedures for obtaining* initial stock and *replacements at System hospitals (EMS Rules).*

C. Drug/Pharmacologic and Supplies Management policies are implemented and monitored by the NWC EMS Medical Director (EMS MD) in cooperation with all members.

D. Drugs and pharmacologics stocked for EMS use shall be of suitable quality, quantity, concentration, and formulation for approved routes of administration per the SOPs and Drug & Supply List. Only those drugs and pharmacologics listed in the SOPs, the System Drug and Supply List, and/or approved by the EMS MD in written format shall be carried on EMS vehicles and given by NWC EMSS personnel.

E. The EMS MD has the overall responsibility for ensuring that systems in place for the safe and secure handling of drugs and pharmacologics are followed.

1. Hospitals and EMS providers must comply with all federal, state, and local laws rules, and guidelines regulating the provision, storage, exchange, and inventory management of drugs and medical supplies, including the laws relating to the handling of controlled substances.

2. Hospitals and EMS providers shall take all reasonable precautions to mitigate risks to patients and staff arising from the use of drugs/pharmacologics, medical supplies & equipment including but not limited to the safe use and security of those items.

3. Medications and pharmacologics shall be issued and stored in their original manufacturer's packaging or if reformulation is necessary, in packaging produced and labeled by a hospital pharmacist.

4. Provider Chiefs/Administrators or their designees are responsible and accountable for the day to day safe and secure handling of drugs and pharmacologics within the operational environment of their agency and must ensure that staff understand and are competent to carry out the duties described in this policy.

5. EMS personnel must maintain their competency in the management of drugs and pharmacologics and to ensure their familiarity with and compliance with changes to therapeutic guidelines as they are adopted in the SOPs.

II. **APPROVING NEW DRUGS AND SUPPLIES**

A. Inclusion of any new drug, supply, solution or equipment on the Standard Drug and Supply List shall be a collaborative process between hospital and prehospital System members unless the EMS MD believes there are unusual and compelling medical reasons for requiring a product based on his or her prerogative alone.

B. New products being considered for use in the NWC EMSS will usually go through the following process prior to being added to the Standard Drug and Supply List:

1. Review by the EMS MD to determine if further evaluation or consideration is warranted or approved. If the EMS MD rejects the product for prehospital use in this System, the investigation process stops at this point.

2. If the EMS MD approves the product for further review, the manufacturer/distributor shall be directed to the Research & Development (R&D) Committee to discuss the merits of the item with potential users.

3. The R&D Committee will provide feedback on the strengths and perceived limitations of a product and may decide to conduct field-testing with the prior authorization of the EMS MD.

4. After evaluation and/or field-testing, the results shall be shared with the Provider and hospital EMS Coordinators/Educators for further discussion and recommendations to the EMS MD.

5. The System is committed to responsible stewardship and agrees that any product purchase that would impact the capital budgets of providers or hospitals shall be brought to the Chiefs/Administrators PRIOR to making a decision for approval or developing a timeline for compliance.

6. The EMS Administrative Director will file a System plan amendment with IDPH.

C. All drugs and equipment not included in the National EMS Education Standards and National EMS Scope of Practice Model (2019) must be approved by IDPH in accordance with the EMS Rules before being used by the System.

IDPH shall either approve the drug and/or equipment, approve the drug and/or equipment on a conditional basis, or disapprove the drug and/or equipment. IDPH's decision shall be based on a review and evaluation of the documentation submitted, the application of technical and medical knowledge and expertise; consideration of relevant literature and published studies on the subject; and whether the drug and/or equipment has been reviewed or tested in the field. The IDPH Director may seek the recommendations of medical specialists and/or other professional consultants to determine whether to approve or disapprove the specific drug(s) or equipment.

D. The EMS MD or designee will ensure the creation of educational materials, mandatory implementation of the education, and documented competency of all users prior to implementing the new drug/pharmacologic.

III. **ISSUING NEW DRUGS AND SUPPLIES**

A. All new products added to the System Drug and Supply List that are consumable, patient exchange items are issued by the hospitals to those Provider agencies assigned to them through the System organizational chart. The cost of the initial inventory will be sustained by system hospitals. All durable medical goods (non-exchange items) will be purchased by the EMS providers.

B. The Resource hospital EMS MD or his designee is responsible for communicating to the Chiefs/Administrators and Hospital and Provider EMS Coordinators (PEMSCs) the name, approved manufacturer(s), type of packaging, amount and cost of product(s) to be added along with a compliance date.

C. An EMS MD shall not approve EMS personnel to use new drugs or equipment unless that individual has completed the IDPH-approved education program and has demonstrated the required competencies and met the performance standards to use that drug or equipment safely and effectively (EMS Rules).

D. An EMS MD is not required to provide new drug or equipment training to System EMS personnel who will not be using the new drugs or equipment.

E. Provider Chiefs/Administrators or their designees are accountable for ensuring that all EMS vehicles are appropriately stocked by compliance dates or a waiver request must be submitted to the Resource Hospital EMS office and approved prior to the compliance date.

F. Provider Chiefs/Administrators or their designees are responsible for notifying their assigned hospital EMSC/educator of all proposed vehicle additions at least three months prior to their implementation to allow for appropriate inventory and budgetary planning for initial stocking.

IV. **EMS DRUG/PHARMACOLOGIC/SUPPLY STORAGE and SECURITY at System HOSPITALS**

A. All drugs and supplies available for EMS exchange shall be stored by hospitals in a "reasonably secure" manner to prevent diversion or tampering with the products. They shall be inspected to ensure the appropriateness of the drug/concentration/packaging, integrity of the packaging, to ensure that they are not near their expiration date (JC), and shall be available to EMS personnel within a reasonable time frame to prevent prolonged down times at the hospitals awaiting exchange.

B. All Controlled Substances must be secured and managed in compliance with DEA laws and regulations. See Controlled Substance policy.

C. Other drugs and products must be kept in areas that are not readily accessible to the public and/or easily removed by visitors. All areas restricted to authorized hospital personnel only are considered “secure” areas. Non-controlled substance drugs stored in these areas do not need to be locked (Joint Commission –[JC]).

D. The security of EMS Medications should be addressed in a hospital’s security management plan (JC standard EC.1.4). As part of this plan, theft, pilferage and tampering should be reported. If medication security becomes a problem, it is expected that the hospital take additional steps to prevent it.

E. If using an Automated Dispensing Machine (e.g. Pyxis, etc), the machine is not a medical control system, but rather a tool that is part of the medication control system. Hospitals must ensure that the proper medication control systems (designed to prevent medication related sentinel events) are still in place when these machines are used.

V. **DRUG/PHARMACOLOGIC/SUPPLY STORAGE and SECURITY at EMS AGENCIES**

A. Drugs and pharmacologics shall be stored per the manufacturer’s recommendations in a safe environment, and in an area that is not accessible by the public from the time of receipt to the point of use or disposal.

B. EMS personnel are personally responsible for the security of all drugs and pharmacologics while they are in their possession (chain of custody). This includes but is not limited to ensuring that ambulances are locked when out of ambulance quarters and not occupied by EMS personnel.

C. EMS vehicles shall be inventoried daily to ensure that drugs and pharmacologics are of suitable quality, quantity, sterility, concentration, formulation and within expiration dates.

D. It is recommended that stock with expiration dates be rotated from reserve and non-transport to front line vehicles within 90 days of expiration to encourage use prior to expiration dates.

E. Provider EMS Coordinators shall make random, unannounced checks of each vehicle within their agency plan at least every six months to ensure compliance with this policy. A record book must be kept at the agency including the identity of the person conducting the checks and retained for a period of two years from the date of the last entry.

F. **CLIMATE CONTROL**

1. Any place where medications are stored shall be sufficiently climate-controlled so that the medications and solutions are kept within the temperature range recommended by the manufacturer.

2. Standards for medications are set by the United States Pharmacopeial Convention Inc. (USP), a nongovernmental entity that establishes standards intended to ensure the quality of medicines and other healthcare technologies. The role of USP and its "National Formulary" (USP-NF) is recognized under the Federal Food, Drug and Cosmetic Act, including their authority to prescribe the packaging, storage, and distribution of medications.

3. Most medications used by EMS are intended for storage at "**controlled room temperature**". "A temperature maintained thermostatically that encompasses the usual and customary working environment of 20°-25° C (68°-77° F) that results in a mean kinetic temperature calculated to be not more than 25° C; and that allows for excursions between 15°-30° C (59°-86° F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40° C are permitted, as long as they do not exceed 24 hours. Spikes above 40° C may be permitted if the manufacturer so instructs. Articles may be labeled for storage at "controlled room temperature" or at up to 25° C (86° F), or other wording based on the same mean kinetic temperature. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variations.

Medication	Recommended Storage Temperature
Adenosine	15° - 30° C (59°-86° F); Do not refrigerate
Albuterol sulfate	2° - 25° C (36°-77° F)
Amiodarone	Controlled room temp 25° C (77° F);
Atropine	15° - 30° C (59°-86° F)
Diazepam	At or below 25° C (77° F)
Diltiazem	25° C (77° F); excursions permitted to15° - 30° C (59°-86° F)
Diphenhydramine	15° - 30° C (59°-86° F); protect from freezing
Dopamine	Controlled room temp -15° - 30° C (59°-86° F);
Epinephrine 1:1,000	15° - 30° C (59°-86° F);
Epinephrine 1:10,000	15° - 30° C (59°-86° F);
Glucagon	Controlled room temp 20°-25° C (68°-77° F)
Ipratropium	2° - 25° C (36°-77° F)
Lidocaine 2%	2° - 25° C (36°-77° F)
Magnesium	15° - 30° C (59°-86° F); protect from freezing
Midazolam	15° - 30° C (59°-86° F);
Naloxone	Controlled room temp -15° - 30° C (59°-86° F);
Sodium bicarb	15° - 30° C (59°-86° F);
Normal Saline	The expiration dating is based on stability data generated from product samples stored at the equivalent of a constant 25°C (77° F). While stored under labeled conditions, our product remains pharmaceutically acceptable. Prolonged storage at higher temperatures may accelerate concentration and pH changes in the final product (Baxter)

4. Items requiring **warming** (at least 1 bag 1000 mL NS) must be stored in a heating unit, solely for that purpose. Temperatures of warming units/drawers must be recorded daily by a designated person within the agency. We do not recommend heating IV solutions in a microwave oven.

Warming recommendations for intravenous (IV) solutions in plastic bags:

- IV solutions of volumes 150mL or greater can be warmed in their plastic overpouches to temperatures not exceeding 40°C (104°F), and for a period no longer than 14 days.
- Label bags with warming expiration date before placing in the warmer.
- Once the VIAFLEX plastic containers have been in the warming cabinet for their maximum time period, remove the container from the warming cabinet and identify as having been warmed. They should not be subsequently returned to the warmer.
- They may continue to be used until the labeled expiration date from the manufacturer provided they have not been warmed more than once (Baxter, 2015).

Note: Intentional warming of IV containers does not affect the sterility of those containers and the solutions they contain. IV containers are terminally sterilized at higher temperatures and container seals are able to withstand those temperatures. Unless the container has been breached during shipping, handling, or storage, the solution remains sterile throughout its life. Clinicians must check the integrity of all of containers prior to use, whether intentionally warmed or not. The warming temperatures listed in this policy are provided only as a guideline to insure the chemical stability of the warmed products (Baxter, 2015).

5. **Recommended Practice from USP-NF Chapter**

a. Monitor and verify temperature profiles to compare with established limits, especially on hot summer days and cold winter days.

b. On-board cabinets must be insulated and should use active heating and cooling if necessitated by the local climate.

c. Consider using insulated portable carrying cases and, when they are not in use, keep them inside or in a climate-controlled cabinet to maintain controlled room temperature.

d. Consider using portable cases exclusively, instead of on-board cabinets, to facilitate rotation. Time-temperature indicators can be used to monitor temperature exposures of the portable case's entire contents.

e. Consider using time-temperature indicators to monitor individual medication packages, especially for environmentally sensitive and thermally sensitive preparations.

f. All medications should be protected from excessive heat (40° C+). Some medications may need to be stored in a cold and/or dry place, and "environmentally sensitive" medications should not be stored on EMS vehicles unless the storage cabinet is temperature-controlled or individual time-temperature indicators are attached to each medication package.

g. Consider stock rotation on a schedule based on local climate, perhaps every three days or so. The stock should be rotated into a climate controlled environment. Stock rotation may be especially necessary for environmentally sensitive preparations.

h. Consider temperature exposures when parking ambulances. Park in heated and air-conditioned garages if possible. When parking outside, attempt to park in the shade.

i. **Note:** Because the USP classifies this chapter as general information, it does not view compliance as mandatory. The recommendations are offered to guide EMS agencies in efforts to ensure stability of medications and identify practices that will help achieve that goal.

VI. **DRUG REPLACEMENT**

A. EMS supplies shall only be replenished from ED EMS inventories. If ED EMS supplies are depleted, replenishment shall be requested from the Pharmacy Department or alternative/equivalent drugs/supplies only as approved by the EMS MD shall be substituted. Replenishment items shall generally not be taken from ED stock as dose/concentrations may be inconsistent with EMS requirements.

B. EMS medications and supplies shall not be replenished directly through an undocumented handoff from the Pharmacy Department. All exchanges shall be made through a formal and documented request per hospital policy.

C. **REPLACEMENT from AUTOMATED DISPENSING DEVICE**

1. Hospitals must adhere to internal policies and Joint Commission (JC) standards with respect to dispensing ambulance supplies.
2. All medication use standards apply to drugs obtained via an automated dispensing device to the same extent as medications dispensed via the traditional unit-dose drug distribution system or floor stock (JC).
3. IDPH has long approved the use of automated dispensing machines for EMS drugs as long as the hospital has a policy on using these machines for controlled dispensing of supplies and drugs (Leslee Stein-Spencer letter to EMS Coordinators, 3/2/01).
4. Drugs kept in an automated dispensing machine are considered secure as long as access is limited to those people with a password and those people with a password are limited to those who have a need for access to the medications (nurse, pharmacy technician, pharmacists, physicians, paramedics) (JC).

   Hospital that use automated dispensing machines need to determine back-up systems and downtime procedures for the distribution of medications if the machine breaks, power fails, or electronic programming is off line (JC).

D. **Restocking under the Office of Inspector General (OIG) Safe Harbor Regulations**

1. Each System hospital agrees to replace drugs and medical supplies and provide for equipment exchange for items on the NWC EMSS Drug & Supply List on an equal basis for all EMS vehicles that bring emergency patients to their facility (Section 3.20(b) of the EMS Act) in one or more of three categories:
   a. All ambulance providers;
   b. All non-profit and State or local government ambulance service providers (including, but not limited to municipal and volunteer ambulance services providers); or
   c. All non-charging providers (typically volunteer providers) (OIG Rule).
2. A receiving facility can offer restocking to more than one category, and can offer a different restocking program to each category that it restocks, so long as the restocking is uniform within each category (OIG Rule).
3. Except for government-mandated or fair market value restocking protected restocking arrangements must be conducted in an open and public manner. A restocking arrangement will be considered to be conducted publicly if: (i) A disclosure notice is posted conspicuously in the receiving facility's ED or other location where ambulance providers deliver patients that outlines the terms of the restocking program and copies are available to the public upon request (subject to

reasonable photocopying charges) (see sample disclosure form); or (ii) The restocking program operates in accordance with a plan or protocol of general application promulgated by an EMS Council or comparable organization (with copies available to the public upon request). NWC EMSS policy satisfies this requirement.

4. **Fair market value restocking:** This category protects restocking arrangements where an ambulance provider pays the receiving facility fair market value based on an arm-length transaction, for restocked medical supplies (including linens). The final OIG rule does not include the resale of drugs in this category.
   a. The restocking must be at fair market value, and
   b. Payment arrangements must be commercially reasonable and made in advance.

5. **Government-mandated restocking:** This safe harbor protects restocking of drugs and supplies undertaken in accordance with a State or local statute, ordinance, regulations, or binding protocol that requires hospitals or receiving facilities in the area subject to such requirement to restock ambulances that deliver patients to the hospital with drugs or medical supplies that are used during the transport of that patient. This safe harbor does apply to all NWC EMSS provider agencies.

E. Either the hospitals or the ambulance providers must maintain records of restocked items and make the records available to the Dept of Health and Human Services upon request (OIG).

F. All billing or claims submission by the receiving facility, ambulance provider or first responder for replenished drugs and medical supplies used in connection with the transport of a Federal health care program beneficiary must comply with all applicable Federal health care program payment and coverage rules and regulations.

G. Compliance will be determined separately for the receiving facility and the ambulance provider (and first responder) as long as the receiving facility; ambulance provider (or first responder) refrains from doing anything that would impede the other party or parties from meeting their obligations.

H. **Conditions applicable to all safe harbor restocking arrangements**

1. **Appropriate billing of Federal health care programs**: All Federal health care programs must be billed appropriately. The ambulance provider and the hospital may not both bill for the same restocked drug or supply. This includes submitting claims for bad debt.

2. **Documentation requirements:** Either the hospital or the ambulance provider may generate the necessary documentation so long as the other party receives and maintains a copy of it for 5 years. The prehospital patient care report is sufficient to satisfy this requirement if it (i) identifies the drugs and supplies used on the patient and subsequently restocked and (ii) a copy of the report is filed with the receiving facility within a reasonable amount of time. An exchange of linens will be presumed to occur with each run, absent documentation to the contrary.

3. **No ties to referrals:** Restocking arrangements are prohibited that are conditioned on, or otherwise take into account, the volume or value of any referrals or other business generated between the parties for which payment may be made in whole or in part by a Federal health care program (other than delivery to the receiving facility of the r patient for whom the drugs and medical supplies are restocked).

4. **Compliance with all other applicable laws**: Both receiving facilities and the ambulance provider must comply with all Federal, State, and local laws regulating ambulance services including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances (OIG Rule).

VII. **Medication administration errors:** Reference Policy R7 Reportable Incidents

VIII. **PROPER DISPOSAL of unused non-controlled substance drugs/pharmacologics**

A. Drugs/pharmacologics removed from their container/packaging, drawn up into a syringe, or engaged (preload) for potential use on a patient and not (fully) administered must be appropriately wasted and discarded at the hospital and presented for exchange.

B. This may be done by disposing of all non-controlled substance medications and supplies in the EMS Pyxis disposal drawer and/or in compliance with individual hospital policies. They shall not be placed on top of EMS Pyxis machines. Controlled substance disposal is addressed in System policy C6 Controlled Substances.

C. Soon to expire medications shall not be put back into active EMS vehicle stock.

IX. **Recalled and medications unsuitable for use**

A. Immediately pull from use.

B. If possible, pull suitable drug from reserve vehicles to ensure adequate supply on front-line ambulances.

C. Store in a locked space until returned to the hospital for exchange.

X. **Out of date medications/supplies**

A. Stock shall be regularly inspected and rotated to ensure that they have not expired**.**

B. The EMS MD may grant authorization to use drugs after their expiration date in situations of shortages without approved alternatives.

XI. **Lost, non-exchanged, misused, or damaged drugs/pharmacologics**

A. The loss or suspected loss or misuse of any drug or pharmacologic must be reported according to the R-7 Reportable Incidents Policy within the same shift of the discovery.

B. Any drug/supply that is lost, stolen, damaged or not replaced at the time of use will be the fiscal responsibility of the Provider Agency to replace. Provider agencies should contact their designated System hospital to arrange for dispensing of replacement prescription drug products under these circumstances. They may replace other consumable supplies at the designated System hospital or per their own internal policies.

C. Ambulance providers shall be charged the fair market value for the replenished drugs or supplies. Commercially reasonable and appropriate payment arrangements must be made in advance. Nonprofit receiving hospitals may sell to nonprofit ambulance providers at cost (OIG).

References:

IDPH. (Sept 20, 2018). EMS Rules: Section 515.330 EMS Program Plan; Drugs and Equipment.

Illinois Pharmacy Act Subpart R: Pharmacy or drug and medicine service, Section 250.2110.

Dept. of Health & Human Services Office of Inspector General (OIG) (December 4, 2001). Final rule: Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute [FR 65(99), 62979-62991].

U.S. Pharmacopeia

U.S. Food and Drug Administration: General Biologic Products Standards. 21 CFR 610.

Federal Food, Drug and Cosmetic Act, 21 USC 321.

Matthew T. Jordan, M.D., FACEP
EMS Medical Director

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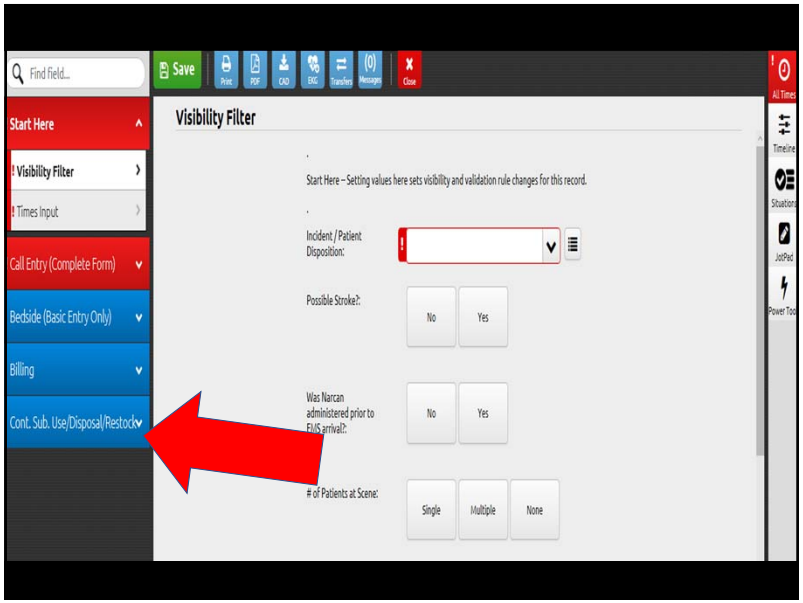
EMS Administrative Director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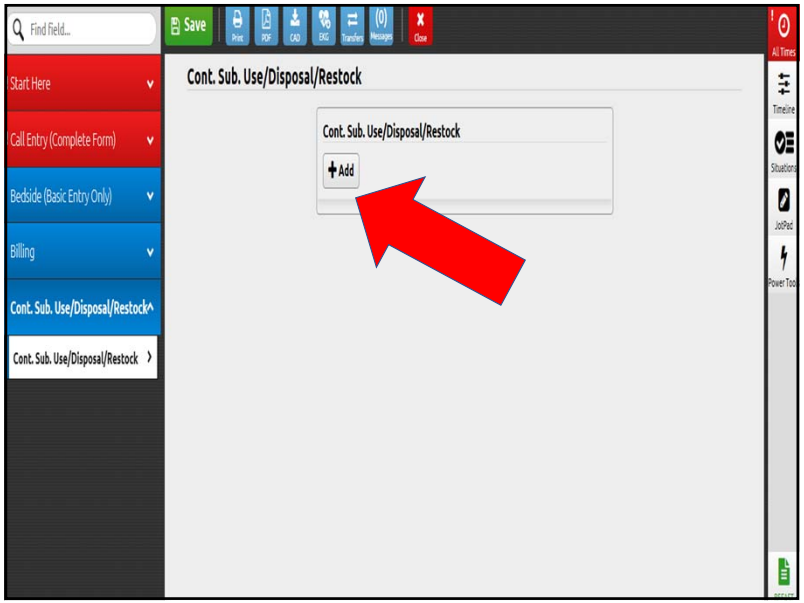
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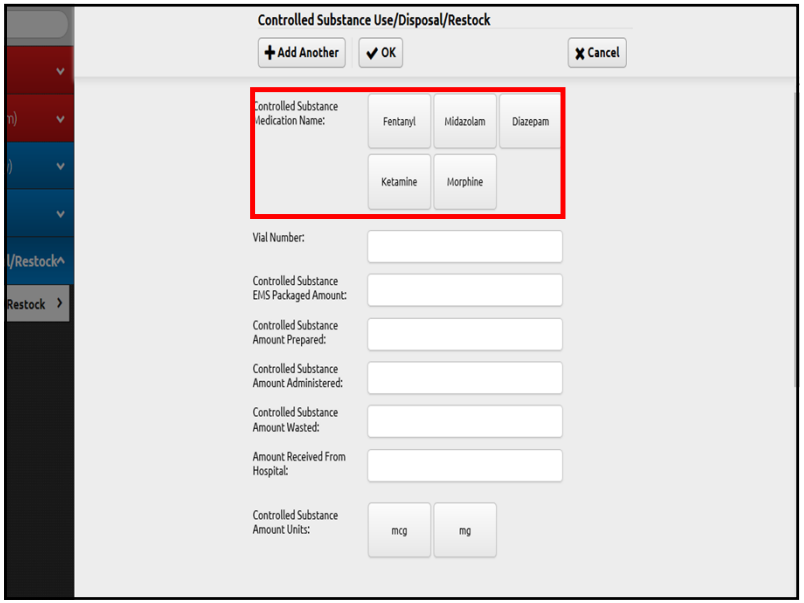
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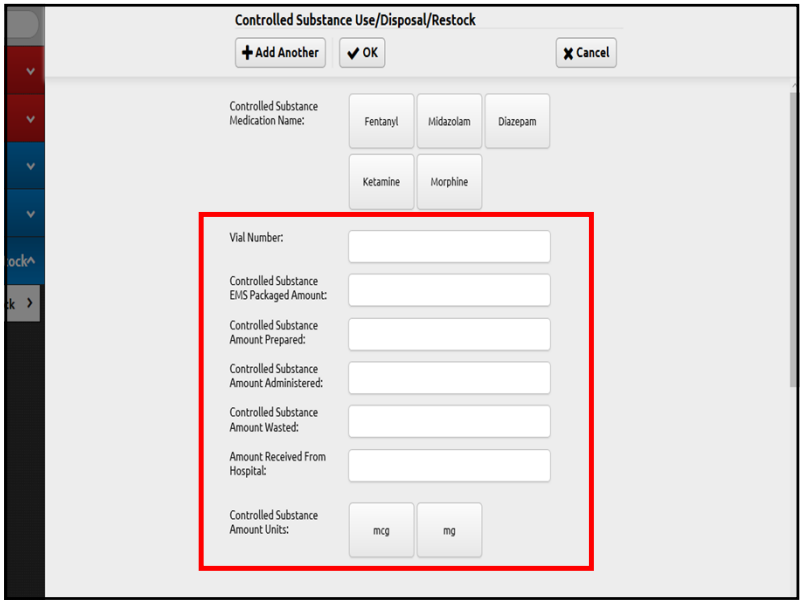
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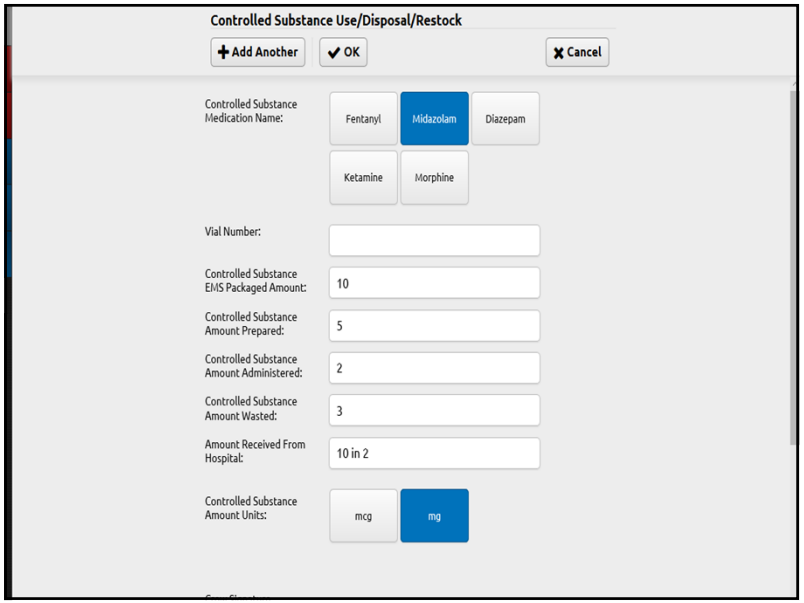
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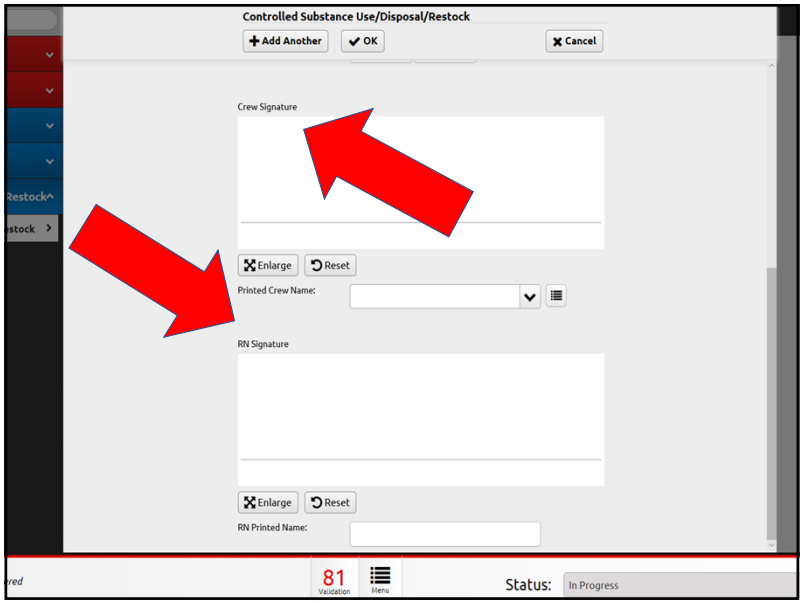
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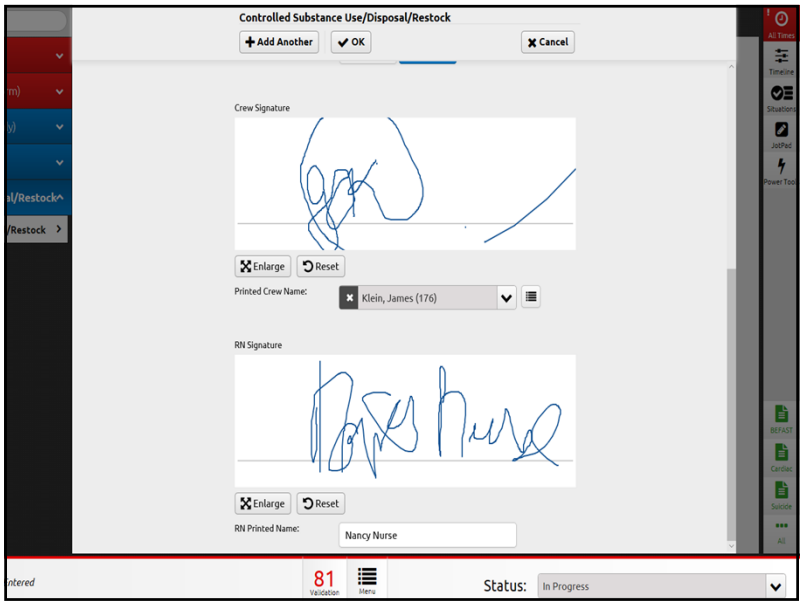
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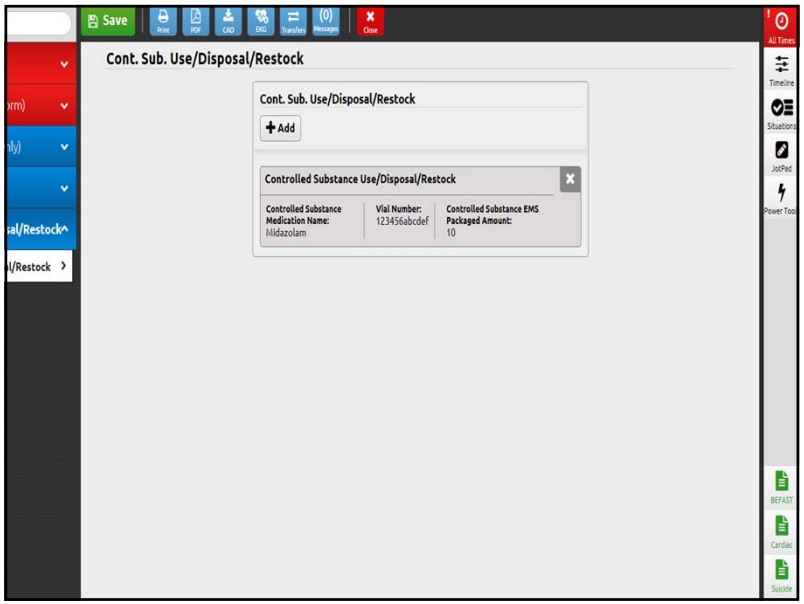
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ILLINOIS DEPARTMENT OF PUBLIC HEALTH
IDPH
PROTECTING HEALTH, IMPROVING LIVES

HEALTH ALERT

JB Pritzker, Governor | Ngozi Ezike, MD, Director

Summary and Action Items

- A novel coronavirus (2019-nCoV) has been detected in Wuhan, China with additional exported cases confirmed in Thailand, Japan, and South Korea. Today, we learned of the first U.S. case, confirmed in Washington state.
- O'Hare International Airport will be one of five airports conducting active screening for illness in passengers entering the US who traveled from Wuhan City, China.
- Patients presenting with fever and respiratory symptoms should be asked at triage about travel to Wuhan, China, or if any known contact with a 2019-nCoV case.
- Suspect Patients Under Investigation (PUIs) should be immediately placed in respiratory isolation.
- Healthcare providers should promptly notify both infection control personnel at their facility and the local health department in the event of a PUI.
- A PUI form should be completed for all suspect person's under investigation.
- Diagnostic specimens for all PUIs, including upper respiratory, lower respiratory and serum samples, should be collected and sent to any IDPH laboratory, in collaboration with your local health department.
- Testing for other respiratory pathogens should be conducted as clinically indicated.

Clinicians are asked to:

1.) Conduct a travel history for individuals presenting with fever and respiratory symptoms.
2.) Promptly isolate all suspect PUIs as per guidance below.
3.) Immediately contact your infection control team and local health department (list below).
4.) Complete the 2019-nCoV PUI form (link below).
5.) Assist with specimen collection and diagnostic testing.

Background

The Centers for Disease Control and Prevention (CDC) and IDPH are closely monitoring an outbreak caused by a novel coronavirus (2019-nCoV) originating in Wuhan City, Hubei Province, China. Coronaviruses are a large family of viruses, some causing illness in humans and others that circulate among animals. Rarely, animal coronaviruses can evolve and infect people and then spread between people such as has been seen with MERS and SARS.

Chinese authorities identified 2019-nCoV, which has so far resulted in more than 200 confirmed human infections in China with six known deaths since late December 2019. Exported cases have since been confirmed in Thailand, Japan, and South Korea with the first U.S. case confirmed today in Washington state. Several countries, including the United States, are actively screening incoming travelers from Wuhan, China.

Many of the patients in the outbreak in Wuhan, China have had some link to a large seafood and animal market, suggesting animal-to-person spread. However, some patients have not had exposure to animal markets. Family clusters have been identified, and infections in health care workers have been reported, suggesting that some level of person-to-person spread is occurring. Investigations are ongoing to learn more about the epidemiologic profile of the virus.

This is a rapidly evolving situation. CDC's 2019-nCoV webpage will be updated with the latest epidemiological information.

Symptoms

Patients who meet the following criteria are considered a PUI for 2019-nCoV.

Clinical Features	&	Epidemiologic Risk
Fever [1] **and** symptoms of lower respiratory illness (e.g., cough, difficulty breathing)	and	In the 14 days before symptom onset: • a history of travel from Wuhan City, China, **OR** • close contact[2] with a person who is under investigation for 2019-nCoV while that person was ill.
Fever [1] **or** symptoms of lower respiratory illness (e.g., cough, difficulty breathing)	and	In the 14 days before symptom onset: • close contact[2] with an ill laboratory-confirmed 2019-nCoV patient

[1]Fever may not be present in some patients, such as those who are very young, elderly, immunosuppressed, or taking fever-reducing medications. Clinical judgement should be used to guide testing of patients in these situations.

[2]Close contact is defined by being within 6 feet (12 meters) or within the room or care area of a novel coronavirus case for a prolonged period of time while not wearing recommended PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection). Close contact can include caring for, living with, visiting, or sharing a healthcare waiting area or room with a 2019-nCoV case OR by having direct contact with infectious secretions of a 2019-nCoV case (e.g. being coughed on) while not wearing PPE. Consider duration of contact and clinical symptoms of ill patient to inform "close contact."

If there is uncertainty, patients should be evaluated and discussed with local health departments on a case-by-case basis. **The exposure locations under Epidemiologic Risk will continue to evolve and are subject to change.**

Diagnosis Testing

Testing for 2019-nCoV is currently only being conducted at the CDC, and approval must be obtained through your local health department. CDC requests all three specimen types: lower respiratory (bronchoalveolar lavage, tracheal aspirate, sputum), upper respiratory (nasopharyngeal AND oropharyngeal swab using synthetic fiber swabs with plastic shafts placed in separate vials with 2-3mL viral transport medium), and serum specimens collected in serum separator tube for diagnosis of 2019-nCoV. Additional specimen types (e.g., stool, urine) may be collected and stored. Specimens should be collected as soon as possible once a PUI is identified regardless of time of symptom onset.

Additional CDC guidance for collection, handling, and testing of clinical specimens is available. Refrigerate specimens at 2-8°C and ship on ice pack by expedited shipping to IDPH for overnight shipment to CDC. An authorization code must be provided by your local health department prior to shipment.

Testing for other respiratory pathogens should not delay specimen shipping to CDC via IDPH. Patient should be tested for commonly circulating viral infections including influenza, RSV, and

other respiratory pathogens. If a PUI tests positive for another respiratory pathogen, consideration regarding additional testing for 2019-nCoV in PUIs should be discussed with public health. This may evolve as more information becomes available on possible 2019-nCoV co-infections.

For biosafety reasons, it is NOT recommended to perform virus isolation in cell culture or initial characterization of viral agents recovered in cultures of specimens from a PUI for 2019-nCoV.

Infection Control

CDC currently recommends a cautious approach to PUIs for 2019-nCoV. PUIs should be asked to wear a surgical mask as soon as they are identified and be evaluated in a private room with the door closed, ideally an airborne infection isolation room if available. Healthcare personnel entering the room should use standard precautions, contact precautions, airborne precautions, and use eye protection (e.g., goggles or a face shield). Immediately notify your healthcare facility's infection control personnel and local health department. At this time, information is lacking to definitively determine a recommended duration for keeping patients in isolation precautions. Duration of precautions and duration a room should remain empty after a PUI vacates it, should be determined on a case-by-case basis in consultation with your local health department.

Increased vigilance should be used with performance of aerosol generating procedures which have been associated with increased risk of transmission of SARS-CoV and MERS-CoV including: tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, and bronchoscopy.

Screening

Screening for travelers from Wuhan began at San Francisco (SFO), New York (JFK), Los Angeles (LAX) on January 17th, 2020. This week, CDC will add entry health screening to two more airports, Chicago (ORD) and Atlanta (ATL). Travelers will also be provided with a Traveler Information Card which lists symptoms that should prompt a visit to a healthcare provider, and instructions to call ahead prior to seeking care. At this time, asymptomatic travelers will not be actively monitored.

Reporting

In the event of a PUI for 2019-nCoV, healthcare providers should immediately notify infection control personnel at their healthcare facility, their local health department or the Illinois Department of Public Health (Phone: 217-782-2016) if unable to reach your LHD. A 2019-nCoV Patient Under Investigation (PUI) form should be completed.

Contact

- For additional information or questions, please contact IDPH Communicable Disease Section at 217-782-2016 or email Isaac.ghinai@illinois.gov; after hours, phone 800-782-7860.
- To report suspected Patients Under Investigation (PUI) cases of 2019-nCoV, please contact your local health department.

Additional Resources

IDPH Website: http://dph.illinois.gov/topics-services/diseases-and-conditions/diseases-a-z-list/coronavirus
CDC 2019 Novel Coronavirus, Wuhan China Situation Summary
https://www.cdc.gov/coronavirus/2019-ncov/index.html

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 20, 2020

Dear Colleague:

To help prevent introduction of a new coronavirus known as 2019 Novel Coronavirus (nCoV) into the United States, CDC is working with US Customs and Border Protection to assess and identify potentially infected travelers arriving on direct or connecting flights from Wuhan, China at these airports: San Francisco (SFO), New York (JFK), Los Angeles (LAX), Atlanta (ATL), and Chicago (ORD). This process will assess travelers coming from Wuhan into the United States. This is an evolving situation, and guidance may change quickly as CDC continues to monitor the situation closely.

We continue to work closely with EMS and other vital partners at US international ports of entry to enhance detection of travelers with possible 2019-nCoV symptoms. *To make accurate assessments of sick travelers, CDC requests that EMS systems stock thermometers on all units responding at US ports of entry.*

Please share this CDC update with EMS units at ALL US airports. We request EMS support to:

- Look for sick travelers arriving from Wuhan, China, who have any of these signs or symptoms: fever, cough, or difficulty breathing.
- If responding to an illness report from a flight:
    - Remove sick traveler(s) from the aircraft to conduct assessment.
- Measure the sick travelers' temperature and check for other symptoms.
- Ask sick travelers if they were in Wuhan, China in the 2 weeks prior to symptom onset.
- If the traveler has any of the above signs or symptoms or otherwise meets CDC's criteria shown on your EMS card, please wear the appropriate PPE as needed, and contact the CDC Quarantine Station within your jurisdiction, available 24/7.
- Station staff will work with EMS to evaluate the traveler's potential illness and exposures to 2019-nCoV, or another illness of public health concern. (If CDC staff are not present at the port of entry, EMS assistance with this evaluation may be requested.)
- Based on the sick traveler's clinical presentation and exposure history, CDC may require sick traveler have a medical evaluation.

If you have any questions about the above, please feel free to contact the CDC Quarantine Station in your jurisdiction at www.cdc.gov/quarantine/QuarantineStationContactListFull.html.

Thank you for your outstanding support and service,

Clive Brown, MBBS, MPH, MSc, DTM&H
Chief, Quarantine and Border Health Services Branch
Division of Global Migration and Quarantine
Centers for Disease Control and Prevention
Encls: CDC Response to 2019 Novel Coronavirus

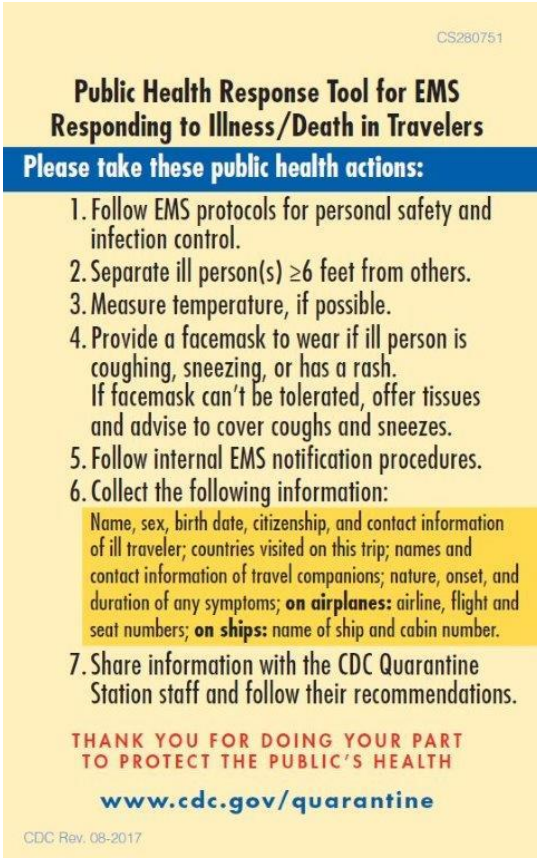
Response to 2019 Novel Coronavirus
CDC Request for Assistance to EMS at US Ports of Entry
January 20, 2020

Signs and symptoms of 2019 Novel Coronavirus (nCoV)
Fever, cough, or difficulty breathing

How you can help
- Be especially vigilant for arriving sick travelers from Wuhan, China with any of the above signs and symptoms.
- If responding to an illness report on a flight:
  - Bring a thermometer and appropriate PPE.
  - Remove sick traveler(s) from the aircraft to conduct assessment.
- Conduct a health assessment and include temperature.
- Ask sick travelers if they were in Wuhan, China in the 2 weeks prior to symptom onset.
- If yes or if meeting any EMS card criteria, please contact the CDC Quarantine Station within your jurisdiction, available 24/7. All contact information located here: www.cdc.gov/quarantine/quarantinestationcontactlistfull.html).
  Station staff will evaluate with EMS the travelers' illness and possible exposures to 2019-nCoV.
  - If CDC staff are not present at the port of entry, EMS assistance with this evaluation may be requested.
- CDC will assess sick travelers and determine whether a medical evaluation is required from a public health standpoint.
- Isolate sick or suspected 2019-nCoV traveler and protect yourself.
  - Ask patient to wear a surgical mask.
  - Implement standard precautions, contact precautions, airborne precautions and use eye protection (e.g. goggles or a face shield).
  - Specific CDC recommendations for healthcare providers are available at: www.cdc.gov/coronavirus/2019-nCoV/infection-control.html

Contact your CDC Quarantine Station
Contact information for your quarantine station is provided on the back of your CDC EMS card. You can also find your CDC Quarantine Station of jurisdiction at:
www.cdc.gov/quarantine/QuarantineStationContactListFull.html
- Call 24/7 your CDC Quarantine Station of jurisdiction to report any sick travelers who have any of the above symptoms and were in Wuhan, China in the 2 weeks prior to symptom onset.

For updated information
This is a rapidly evolving situation—information may change quickly.
- CDC 2019 Novel Coronavirus, Wuhan, China updates: https://www.cdc.gov/coronavirus/2019-nCoV
- CDC Travelers' Health updates: https://wwwnc.cdc.gov/travel/notices/watch/novel-coronavirus-china
- CDC Quarantine Stations Info: www.cdc.gov/quarantine/QuarantineStationContactListFull.html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Public Health Response Tool for EMS Responding to Illness/Death in Travelers

Please take these public health actions:

1. Follow EMS protocols for personal safety and infection control.
2. Separate ill person(s) ≥6 feet from others.
3. Measure temperature, if possible.
4. Provide a facemask to wear if ill person is coughing, sneezing, or has a rash. If facemask can't be tolerated, offer tissues and advise to cover coughs and sneezes.
5. Follow internal EMS notification procedures.
6. Collect the following information:
   Name, sex, birth date, citizenship, and contact information of ill traveler; countries visited on this trip; names and contact information of travel companions; nature, onset, and duration of any symptoms; **on airplanes:** airline, flight and seat numbers; **on ships:** name of ship and cabin number.
7. Share information with the CDC Quarantine Station staff and follow their recommendations.

THANK YOU FOR DOING YOUR PART TO PROTECT THE PUBLIC'S HEALTH

www.cdc.gov/quarantine

CDC Rev. 08-2017

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
IDPH
PROTECTING HEALTH, IMPROVING LIVES

HEALTH ALERT

JB Pritzker, Governor | Ngozi Ezike, MD, Director

Summary and Action Items

1) To alert clinicians to recently reported cases of profound methemoglobinemia secondary to Sodium Nitrite Ingestion
2) Provide information on treatment resources and recommendations

Background

In a ten-day period, three patients with extremely elevated methemoglobin levels have been reported to the Illinois Poison Center. Two of the three patients expired. Two of the individuals are suspected intentional ingestions of sodium nitrite by history, and the third case is consistent by clinical presentation with a sodium nitrite ingestion.

Concurrently, a spike in suicidal sodium nitrite ingestions is being reported by poison centers in various areas around the country.

Potential Exposures and Transmission

Web sites that refer to suicide recipes have mentioned sodium nitrite ingestion as a successful method of self-harm. The compound can be made at home or purchased in bulk from online retailers such as eBay or Amazon.

Symptoms

Presenting symptoms of the above patients included profound cyanosis, shortness of breath and hypotension. Dizziness, confusion, nausea and vomiting may also be seen. Pulse oximetry readings generally do not improve with increased supplemental oxygen. Venous blood when drawn will have a characteristic 'chocolate brown' color. Methemoglobinemia is suggested when there is clinical cyanosis in the presence of a normal arterial pO_2 (P_aO_2).

Treatment

The antidote for this poisoning is intravenous methylene blue and was successful in the resuscitation of one of the recent cases with a level that would have otherwise likely have been fatal if left untreated.

Recommendations for healthcare facilities

Please contact the Illinois Poison Center at 1-800-222-1222 for treatment recommendations for patients presenting with severe methemoglobinemia, and to report cases for public health monitoring. Further acute clinical guidance from the Illinois Poison Center is attached to this alert

Prevention Resources

For a listing of suicide prevention resources, please visit IDPH's Suicide Prevention Webpage.

Public Health Response

November 2019

Potent Synthetic Opioid - Isotonitazene - Recently Identified in the Midwestern United States

cfsre
Redefining Excellence in Forensic Science

NPS DISCOVERY

Purpose: The objective of this public announcement is to notify public health and public safety, law enforcement, clinicians, medical examiners and coroners, laboratory personnel, and all other related communities about new information surrounding the emergent synthetic opioid isotonitazene.

Background: Synthetic opioids are chemically manufactured drugs, often associated with unknown biological effects and health risks, a dangerous combination for any recreational drug user. Synthetic opioids are often prepared in powder or tablet form and can be mixed with street level traditional opioids. In the United States, a staggering number of deaths have been reported in recent years linked to synthetic opioid use. The primary adverse effect most commonly reported in association with synthetic opioid use is respiratory depression, often leading to death.

Summary: Isotonitazene is a potent synthetic opioid bearing structural resemblance to etonitazene, a synthetic opioid that is nationally and internationally controlled. Isotonitazene is dissimilar in structure to popular synthetic opioids typically encountered in forensic casework (e.g. fentanyl analogues, U-series analogues). Isotonitazene and similar analogues (e.g. etonitazene, metonitazene, and clonitazene) were first synthesized and reported in the literature in the 1950s. Pharmacological data suggest that this group of synthetic opioids have potency similar to or greater than fentanyl based on their structural modifications. Etonitazene is reported to be the most potent of the group followed by isotonitazene and metonitazene. The toxicity of isotonitazene has not been extensively studied but recent association with drug user death leads professionals to believe this new synthetic opioid retains the potential to cause widespread harm and is of public health concern. Isotonitazene has been identified in eight blood specimens associated with postmortem death investigations in the United Stated since August 2019. Isotonitazene was first reported in August 2019 based on the results from seized drug and toxicology casework in Europe (Belgium) and Canada (Alberta); the Canadian toxicology case was collected in March 2019.

Demographics

Age:
- Avg. 42, Med. 42.5
- Range: 20's to 60's

Sex:
- Male (n=6), Female (n=2)

Case Type:
- Postmortem (n=8)

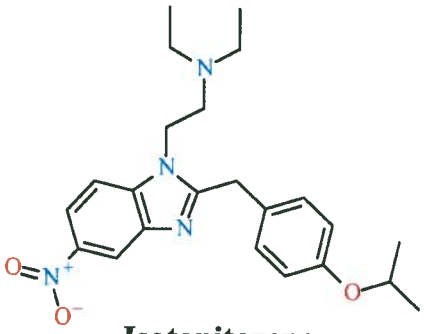
Specimen Type:
- Blood (n=8)

Date of Collection:
- Aug. to Oct. 2019

Other Notable Findings:
- Etizolam (n=6)
- Fentanyl (n=3)
- U-47700 (n=1)
- Piperidylthiambutene (n=1)

Recommendations for Public Health

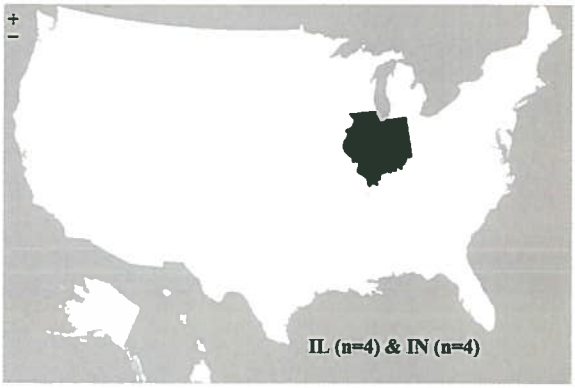
- Implement surveillance for rapid identification of drug overdose outbreaks.
- Engage local poison centers and clinicians to assist with treatment of affected patients.
- Track and monitor geographical drug distribution and trends.
- Track demographics and known risk factors for decedents and overdose patients.
- Raise awareness about the risks and dangers associated with opioid use.
- Make naloxone available to recreational drug users.



Isotonitazene

Recommendations for Clinicians

- Become familiar with the signs and symptoms associated with synthetic opioid use (e.g. sedation, respiratory depression).
- Naloxone should be administered to reverse critical respiratory depression. Be aware that clinical conditions may change rapidly and unpredictably after naloxone administration due to precipitation of withdrawal.
- Be mindful that illicit drugs have limited quality control, containing undeclared substances that impact the expected clinical effects or findings.
- Counsel about the dangers of synthetic opioid products and other drugs.



Recommendations for MEs & Coroners

- Test for new synthetic opioids and their biomarkers in suspected opioid overdose cases.
- Be aware that ELISA screening for synthetic opioids may not be specific or specialized for the newest generation of compounds; consider mass spectrometry-based screening.
- Be aware that concentrations of synthetic opioids in biological specimens can vary and GC-MS sensitivity may not be adequate.

Recommendations for Laboratories

- Utilize analytical data available publicly for the identification of isotonitazene and other synthetic opioids if reference standards are not available.
- Utilize previously developed non-targeted testing protocols or develop sensitive and up-to-date testing procedures for synthetic opioids.
- Prioritize analytical testing of seized drug samples taken from drug overdose scenes during death investigations.
- Share data on synthetic opioid drug seizures with local health departments, medical examiners, and coroners.

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References and Related Articles:

- Hunger, A., Kebrle, J., Rossi, A., Hoffmann, K. (1957) Synthesis of analgesically active benzimidazole derivatives with basic substitutions. *Experientia*, 13, 400-401.
- Hoffmann, K., Hunger, A., Rossi, A. (3 May 1960). Patent US2935514A – Benzimidazoles.
- Police warning of new deadly opioid found on Calgary streets

Rapid NPS Testing Now Available:

If your agency suspects synthetic opioid toxicity with no identifiable cause of death or your jurisdiction is noticing an increase in overdose patients requiring analytical testing, contact NPS Discovery at the Center for Forensic Science Research and Education; a non-profit organization in collaboration with DOJ and CDC, which has received funding to provide rapid testing of novel drug outbreaks in the United States.

Website: npsdiscovery.org **Email:** npsdiscovery@cfsre.org