



UNCLASSIFIED

DEPARTMENT OF DEFENSE
FEDERAL COVID-19 RESPONSE
200 INDEPENDENCE AVENUE
WASHINGTON, DC 20201

SA

18 May 2021

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Secure disposal of vaccine vials and packaging recommendations

1. Recommendations for secure disposal of vaccine vials and packaging were issued by this office on 02 February, 2021 and distributed to Federal Partners and Agencies. The threat of fake or counterfeit vaccines still exists. This memorandum reiterates the recommendations issued on 02 February 2021 and adds an additional recommendation action to reduce the threat of fake or counterfeit vaccines.

2. The following recommended actions will further protect COVID 19 vaccine empty vials and packaging to reduce counterfeit efforts:

a) Action 1 (Preferred method): Treat vials and packaging similarly to medical waste by placing in red sharps container; or

b) Action 2: Deface all or safely crush materials so it cannot be reintroduced or reproduced. After the products are sufficiently defaced, then dispose with regular waste.

c) Action 3: Dispose of unused vaccine appropriately – DO NOT send back to manufacturing company or return in shipper boxes. Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine predrawn by providers—these cannot be returned and should be discarded according to state requirements. Please refer to CDC Vaccine Storage and handling Toolkit (<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>).

3. Vaccines are only available and administered through State authorized vaccination locations. Vaccines are currently only distributed to State, Tribal and Territorial governments as well as participating pharmacies and are only administered through State approved medical entities. Non-medical companies or private persons are not authorized to provide, sell, or administer vaccines.

a) Any offers related to the sale or use of COVID vaccines, not from a medical provider, should be considered suspicious and reported to the appropriate state or jurisdiction. This may include: State or local Department of Health; the US Department of Health and Human Services, Office of the Inspector General at 1-800-HHS-TIPS or www.oig.hhs.gov; or submit a tip to the Federal Bureau of Investigation to: www.tips.fbi.gov.

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4. Request all parties publish the above recommended actions to their Frequently Asked Questions page and distribute through official channels.

5. Please direct all questions on secure disposal to Thomas Brannon, Office of Inspector General, HHS at (305) 407-6763.



CARY J. COWAN JR.
Brigadier General, U.S. Army
Director of Security and Assurance

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DISTRIBUTION

Department of Health and Human Services Office of the Inspector General
Federal Bureau of Investigation Intellectual Property Rights Unit
Food and Drug Administration Office of Criminal Investigations
Centers for Disease Control and Prevention COVID-19 Response Vaccine Task Force
Department of Homeland Security Homeland Security Investigations
Cybersecurity and Infrastructure Security Agency



HEALTHCARE & PUBLIC HEALTH SECTOR

03 March 2021

LIR 210303006

Improperly Discarded COVID-19 Vaccines Could Be Exploited to Commit Fraud

References in this LIR to any specific commercial product, process or service or the use of any corporate name herein is for informational purposes only and does not constitute an endorsement, recommendation, or disparagement of that product, process, service or corporation on behalf of HHS-OIG or the FBI.

The Department of Health and Human Services, Office of Inspector General (HHS-OIG), the Food and Drug Administration Office of Criminal Investigations (FDA-OCI), and the FBI Criminal Investigative Division, in coordination with the FBI's Office of Private Sector (OPS), prepared this Liaison Information Report (LIR) to inform healthcare providers and public health entities about risks posed by improper disposal of COVID-19 vaccines and vaccine-related materials.

While there are no reported instances of individuals re-using COVID-19 vaccine-related materials, HHS-OIG, FDA-OCI, and the FBI remain alert to the potential fraudulent re-use of empty, spoiled, or expired vials, syringes, packaging, and containers. This type of activity could jeopardize the vaccination campaign against COVID-19 and pose a threat to public health.

As the effort to vaccinate more Americans expands to larger facilities not typically equipped with medical waste disposal, all vaccine providers should be careful when disposing COVID-19 vaccine-related materials including syringes, vials, vial container boxes, vaccination record cards, and shipment or tracking records. In addition to the recommendations made by the Department of Defense Federal COVID Response in their 2 February 2021 memorandum titled "Secure Disposal of Vaccine Vials and Packaging Recommendations," the FBI and its partners have identified the following best practices, which vaccine providers may consider adopting to reduce instances of vaccine fraud:





- Make sure all individuals handling vaccines are familiar with proper disposal guidelines
- Tear or shred empty boxes containing vaccine vials
- Return any ultra-low temperature packaging as instructed
- Verify that tamper-proof seals are intact before opening new vaccine vial containers
- Discard used syringes and empty vials in designated sharps disposal containers
- Be on the lookout for any unauthorized personnel attempting to access medical waste
- Do not leave vaccine vials, syringes, container boxes, or other packaging unsecured or unattended
- Do not keep or share empty vials, containers, or packaging as "souvenirs"
- Do not accept vaccine vials which are individually shipped or delivered as pre-filled syringes

To report suspicious activity involving vaccine fraud, please contact the appropriate government agency in your state or jurisdiction, as well as the National Center for Disaster Fraud (1-866-720-5721 or www.justice.gov/disastercomplaintform); HHS-OIG (1-800-HHS-TIPS or www.oig.hhs.gov); FDA OCI (<https://www.fda.gov/ReportCriminalActivity>); or the FBI (www.tips.fbi.gov).



This LIR was disseminated by OPS’s Information Sharing and Analysis Unit. Send questions and requests to the FBI Private Sector Coordinator at your FBI Field Office (www.fbi.gov/contactus/field-offices).

Traffic Light Protocol (TLP) Definitions

Color	When should it be used?	How may it be shared?
<p>TLP:RED</p>  <p>Not for disclosure, restricted to participants only.</p>	<p>Sources may use TLP:RED when information cannot be effectively acted upon by additional parties, and could lead to impacts on a party's privacy, reputation, or operations if misused.</p>	<p>Recipients may not share TLP:RED information with any parties outside of the specific exchange, meeting, or conversation in which it was originally disclosed. In the context of a meeting, for example, TLP:RED information is limited to those present at the meeting. In most circumstances, TLP:RED should be exchanged verbally or in person.</p>
<p>TLP:AMBER</p>  <p>Limited disclosure, restricted to participants' organizations.</p>	<p>Sources may use TLP:AMBER when information requires support to be effectively acted upon, yet carries risks to privacy, reputation, or operations if shared outside of the organizations involved.</p>	<p>Recipients may only share TLP:AMBER information with members of their own organization, and with clients or customers who need to know the information to protect themselves or prevent further harm. Sources are at liberty to specify additional intended limits of the sharing; these must be adhered to.</p>
<p>TLP:GREEN</p>  <p>Limited disclosure, restricted to the community.</p>	<p>Sources may use TLP:GREEN when information is useful for the awareness of all participating organizations as well as with peers within the broader community or sector.</p>	<p>Recipients may share TLP:GREEN information with peers and partner organizations within their sector or community, but not via publicly accessible channels. Information in this category can be circulated widely within a particular community. TLP:GREEN information may not be released outside of the community.</p>
<p>TLP:WHITE</p>  <p>Disclosure is not limited.</p>	<p>Sources may use TLP:WHITE when information carries minimal or no foreseeable risk of misuse, in accordance with applicable rules and procedures for public release.</p>	<p>Subject to standard copyright rules, TLP:WHITE information may be distributed without restriction.</p>



HEALTHCARE & PUBLIC HEALTH SECTOR

22 April 2021

LIR 210422002

Criminal Actors Continue to Successfully Capitalize from the Sale of Counterfeit COVID-19 Health and Safety Products

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The FBI's New York Field Office, in coordination with the Criminal Investigative Division, and the Office of the Private Sector (OPS) produced this Liaison Information Report (LIR) to inform the Healthcare and Public Health Sector of criminal actors' financially capitalizing on the production and distribution of counterfeit COVID-19 related health and safety products and ways to avoid becoming victims of counterfeit COVID-19 products.

Since the spring of 2020, mass production of disinfecting cleaning products and personal protective equipment (PPE) has continued to steadily increase. However, criminal actors continue to prey on consumers' COVID-19 fears seeking opportunities to advertise and profit from the sale of counterfeit PPE, often sold at double the price than legitimate PPE. As a result, consumers unknowingly turn to nefarious sources of PPE, including online websites intended to defraud consumers with no intention of delivering purchased goods.

- In February 2021, local authorities seized 1.7 million counterfeit N95 face masks from a warehouse located in Queens, New York. Criminal actors advertised the face masks to unsuspecting consumers as legitimate N95 respirators masks. In addition, criminal actors marketed the sales price for face masks from \$2.95 to \$3.25 each.
- In mid-February 2021, the Department of Homeland Security (DHS) seized over 11 million counterfeit N95 masks in seizure operations in five states over a two-week period. DHS notified six thousand possible buyers of these masks, in at least 12 states. Some of the potential buyers of these masks included hospitals and medical facilities.
- In late February 2021, FBI, DHS-HSI, and Customs and Border Protection (CBP) seized 460,000 counterfeit N95 surgical masks at a facility in Washington state. These masks were intended to be sold to first-responders and health care workers.
- In November 2020, criminal actors used various fraudulent websites to falsely advertise disinfecting cleaning products. Consumers placing orders through the fraudulent websites never received their orders or were instead shipped unsolicited items, such as a pair of socks.







The FBI encourages individuals and organizations to verify with the manufacturer whether a product is authentic, and if the vendor is authorized to sell their products. In addition, the FBI recommends:

- Buyers do not send full payment for large quantities of PPE before products are delivered and verified as authentic.
- Buyers use caution when purchasing health and safety products from sellers with little or no prior history of selling these products.
- Buyers avoid responding to unsolicited messages offering COVID-19-related health and safety products for sale.

To report suspicious activity involving counterfeit PPE, please contact the appropriate government agency in your state or jurisdiction, as well as the National Center for Disaster Fraud (1-866-720-5721 or www.justice.gov/disastercomplaintform); the National Intellectual Property Rights Center (www.iprcenter.gov); HHS-OIG (1-800-HHS-TIPS or www.oig.hhs.gov); or the FBI (www.tips.fbi.gov).

OPS’s Information Sharing and Analysis Unit disseminated this LIR; please direct any requests and questions to your FBI Private Sector Coordinator at your [local FBI Field Office](https://www.fbi.gov/contact-us/field-offices): <https://www.fbi.gov/contact-us/field-offices>.

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