

Healthcare Compliance Issues for Medical Drones

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By Michael H. Cohen

Advances in drone technology have begun to entice developers and medical care providers. There are numerous projects already in development that will use drones to help deliver medicine and medical supplies, help seniors, and a host of other possible medical uses.

The legal issues involving how these devices will be regulated by the FDA (as a medical device or for other reasons) and other agencies are just beginning. This article explores many of the potential uses of drone technology. As with new innovations, developers and medical providers need to review the lines between the business aspect of this technology and the medical needs of the patients. Our experienced healthcare providers will review many different drone medicine issues including:

- Whether Stark Law, the Anti-Kickback Statute, or other anti-referral laws apply? When can and when can't developers provide incentives to medical practices to use the developer's drone technology? When can a physician have and when can't he/she have an interest in a service that uses drone technology?
- Whether the corporate practice of medicine laws apply? Generally, only doctors can provide medical advice. To the extent the drones are considered medical, there will need to be a discussion about who can own the drone technology company.
- Who can prescribe and administer drone technology that has a medical component?
- Does HIPAA apply if the drone technology includes any electronic information about the patient?
- Many other legal questions depending on the scope and applications of the medical drone technology.

DRUG AND MEDICAL DEVICE MANUFACTURERS NEED TO COMPLY WITH THE ACA'S SUNSHINE ACT – PART ONE

The Sunshine Rule of the Affordable Care Act requires that drug and medical device manufacturers disclose to CMS any payments they made for the benefit of physicians regarding the drugs or devices.

STARK LAW EXCEPTIONS THAT MIGHT APPLY TO YOU

In today's video, we discuss some exceptions to Stark Law, which deals with improper referrals by physicians and healthcare practitioners.

CAN I OWN A MEDICAL PRACTICE IF I AM NOT A DOCTOR? AN OVERVIEW OF CORPORATE PRACTICE OF MEDICINE

We spoke about a series of webinars talking about a trending topic in the legal aspects of corporate medicine, Management Services Organization. And with much anticipation, we bring you – Part II [...]

Drones and the delivery of medications or other health services

Many publications such as Very Well Health have begun to review the benefits of drone technology for the practice of medicine. Very Well Health discussed the following pros and cons of using drones to deliver prescription medication to the homes to patients. For example, Zipline, a leading drone manufacturer is working with Magellan Health and Intermountain Healthcare to deliver prescription medications and medical supplies via drone to a patient's home. The company is already planning to make deliveries in Charlotte, North Carolina and there are plans to service Salt Lake City, Utah – pending FAA (Federal Aviation Administration) approval.

The drones, which are battery-operated can make medical deliveries in about 30 minutes – as compared to hours or days for more traditional services. According to Zipline, *“autonomous aircraft are much more sustainable and fuel-efficient per delivery and also reduce congestion and wear and tear on the highways.”* Zipline already is delivering medical products in Rwanda and Ghana. During the pandemic, Zipline was able to deliver personal protective equipment to North Carolina frontline healthcare workers. The company has also delivered, as of the date of the Very Well Health article, 650,000 COVID-19 vaccines.

The benefits of drone medical delivery

The advantages to drone delivery of medical products according to Very Well Health include getting necessary medical products to people who don't have transportation or who cannot drive due to chronic health problems. The delivery services also mean deliveries can be made according to the patient's schedule.

Drone delivery is especially helpful in rural areas and any areas where the location may be hard to reach or difficult to traverse – such as islands, wetlands, or mountains. Drone delivery services help ensure the patient gets the medications promptly and with less personal contact which can reduce the possibility of spreading infectious diseases.

Drone delivery could be especially useful when disasters happen.

Drone delivery generally works by having a doctor, nurse, or health technician send a request to the drone company. The drone then delivers medications, vaccines, antivenoms, antibiotics, blood transfusions, and many other medical products. The product is dropped by parachute so that the product lands at a rate of speed that should prevent the medication or medical product from being damaged. The drone then flies back to the company launch site.

Concerns about using medical drone services

A few of the disadvantages of medical drone services include the following:

- Storage issues if the medications need to be kept at a certain temperature and a specific humidity level. *“In 2021, Zipline partnered with Pfizer to complete the first long-range drone delivery of COVID-19 vaccines, which must be stored at extremely cold temperatures.”*
- The expense of building and maintenance of the drone
- Equipment failure
- Training costs
- Possible damage or theft of the medications and other medical equipment
- Privacy concerns

- Weather-related challenges such as rain, snow, heat, cold, and wind
- Battery-related capabilities
- Fuel issues
- Drone propellor function

There are regulations (or will likely soon be regulations) that monitor the path of the drone and the number of drones that can be in the sky.

Drones generally land on a person's front yard, backyard, or driveway. This strategy works well for homeowners. The strategy can require more work for apartment renters.

"Another big disadvantage of drone delivery would be bypassing the ability for patients to speak directly with their pharmacist about any questions or concerns regarding their medications." Many patients like to ask questions of their pharmacists when they pick up their prescriptions or medical supplies.

Other concerns include insurance coverage, the cost of the delivery, and what happens if there's a drone accident.

Drone medical deliveries – the next stages

Most Americans live within five miles of a pharmacy. While there would seem to be substantial benefits for people in rural or remote locations, the question begs how practical medical drones are for urban areas. Very Well Health adds that the delivery of medications and medical products *"will require the involvement of multiple federal agencies including the FAA, Federal Trade Commission, Food and Drug Administration, Drug Enforcement Agency, and the Department of Health and Human Services."* Currently, the expectation is that medical drones will primarily be used to test their benefits and risks.

Additional uses of medical drones

According to [Drones in HealthCare](#), medical drones are being developed for purposes other than delivering medications. Drones, like mobile apps, wearable technology, telemedicine, robots, and artificial intelligence are helping provide medical care throughout the country.

In addition to helping people in their homes, drone delivery services could work with nursing homes that often, on average, have more patients in need of medical care than the general public. Drones could also help seniors stay in their homes instead of having to move into a nursing home.

- Drones could help deliver meals to people who can't make their own meals
- Drones could help monitor patients with dementia.
- Drones could possibly help patients who are having cardiac problems and other medical orders that require a defibrillator.
 - *"Automated external defibrillators (AED) [could] fly to the patient in a public space to provide rapid defibrillation for ventricular fibrillation. No longer would a person have to obtain AEDs from a specific location that may be challenging to find in a rapid fashion. Simply summon the AED with the push of a button or smartphone app."*

Drone deliveries can also be useful inside hospitals. Drones can make deliveries from floor to floor and building to building – faster than making the deliveries by walking or through pneumatic tube systems. Other factors that affect how well drone medical services work in hospitals are GPS signals and radio signals – which work outdoors but not as well indoors. As with most technology, there are concerns that drones can affect the jobs of various healthcare workers.

Drones could be designed to deliver more than just medications. Drones could be programmed to sort laundry, grab a glass of

water, or clean around the home. The psychology of having drones fly around a home needs to be considered.

A drone is also referred to as an unmanned aircraft system (UAS).

Forbes profiled a few other medical uses for drone technologies. One interesting possibility is to use drones equipped with cameras and a display screen so the patient can use [telehealth services](#) from their home or any other location to speak with a doctor. Drones can also be designed to enable patients to administer self-lab tests. In this way, the telehealth service could be combined with some diagnostic services.

According to the US NIH:

“Drones are used for surveillance of disaster sites, areas with biological and chemical hazards, and tracking disease spread. It has been shown that drones can gather information about the number of patients in need of care and triage in high-risk environments.”

“Drone technology has been used to detect health hazards, such as heavy metals, aerosols, and radiation.”

“The ability of drones to acquire real-time, high-resolution temporal and spatial information at low cost makes them viable for epidemiology research.”

Drone technology is helping provide medical care in many ways. A primary way is the delivery of medications and medical supplies – especially to remote areas. Drone technology may also help when disasters strike, with medical research, and with the use of telemedicine. Drone manufacturers and medical practices need to understand when and how the FDA, the FTC, and other federal or state agencies may regulate drone technology. Companies need to review referral arrangements, medical supervision issues, and many other healthcare issues – with experienced healthcare attorneys.

Developers, transit systems, hospitals, and health practices that are using drone technology for medical care should [contact](#) Cohen Healthcare Law Group, PC to review the federal and state legal compliance issues (in the health sector) that apply. Our [experienced healthcare attorneys](#) advise manufacturers, medical practices, and healthcare companies and providers about healthcare compliance laws and regulations.

[Contact our healthcare law](#) and [FDA attorneys](#) for legal advice relevant to your healthcare venture.