



December 18, 2020

**ILLINOIS HEALTH AND HOSPITAL ASSOCIATION
M E M O R A N D U M**

TO: Chief Executive Officers, Member Hospitals and Health Systems
Chief Medical Officers
Chief Nursing Officers
General Counsel
Government Relations Personnel
Risk Management & Patient Safety Personnel
Emergency Department Directors

FROM: A.J. Wilhelmi, President & CEO
Karen Harris, Senior Vice President and General Counsel

SUBJECT: Pfizer Vaccine – Use of Additional Doses in Vials

As you are aware, the Food and Drug Administration (FDA) granted an emergency use authorization (EUA) to Pfizer, Inc. for its BNT162b2 mRNA COVID-19 vaccine.

The first shipments of the vaccine have been shipped and it has been discovered that although the vaccine vials are supposed to hold five doses, some vials may have enough for a sixth or even a seventh dose.

As of the date of this memo, the FDA has not issued a formal announcement authorizing or amending the Pfizer vaccination approval documents to address this issue. However at 6:14 p.m. on December 16, the FDA tweeted:

The FDA is aware that some vials of the Pfizer-BioNTech #COVID19 Vaccine have contained extra product after five doses are obtained. The agency is working with Pfizer to determine the best path forward, and will share additional updates as we have them.

At this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial, pending resolution of the issue.

However, since the vials are preservative free, it is critical to note that any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one.

Additionally, the State of Illinois issued a notice ([click here](#)) that recommends following FDA and CDC guidance on this issue.

Since additional doses could significantly increase the U.S.' scarce early supply of this vaccine, many hospitals have inquired whether they may use these additional doses and, if they do, whether the PREP Act's liability immunity protections will cover such usage.

Although each hospital must conduct its own legal and risk tolerance analysis, it appears that the PREP Act's liability immunity protections could cover utilization of the additional doses of the Pfizer vaccine.

See background legal analysis supporting this statement ([click here](#)).

The information provided in this memorandum does not, and is not intended to, constitute legal advice; instead it is intended for general informational purposes only. Each hospital is encouraged to consult their legal counsel and make their own legal and risk analysis regarding this issue.

In making a determination as to whether additional doses can be obtained from a vial, please also consider the following:

- The remaining liquid in a vial must make up a full dose.
- Do not pool from multiple vials to create an additional dose, as this product is preservative free.
- The Pfizer vaccination vials only come with 5 syringes so you will need an additional sufficient supply of syringes.
- If the next shipment of the vaccine does not contain vials that also have the surplus amount, you may not have sufficient supply for the 2nd required dose for the recipient.

If you have any questions, please contact Karen Harris at 630-276-5548 or kharris@team-iha.org.