

December 4, 2020

ILLINOIS HEALTH AND HOSPITAL ASSOCIATION MEMORANDUM

- TO: Chief Executive Officers, Member Hospitals and Health Systems Chief Operating Officers Chief Medical Officers Chief Nursing Officers Chief Quality Officers Chief Financial Officers Emergency Preparedness Contacts Emergency Department Directors Behavioral Constituency Section Government Relations Personnel In-House Counsel Public Relations Directors
- FROM: A.J. Wilhelmi, President & CEO Tim Nuding, Senior Vice President, Member Services & Corporate Finance Keneatha Johnson, Director, Quality, Safety and Health Policy

SUBJECT: IHA COVID-19 Update – State Announces Initial Phase of Vaccine Distribution

At the state's daily COVID-19 press briefing this afternoon, Governor J.B. Pritzker and Illinois Department of Public Health (IDPH) Director Dr. Ngozi Ezike, for the first time, announced details of the initial phase (Phase 1a) of the state's COVID-19 vaccine distribution plan that is expected to begin in mid-December.

In phase 1, the State expects to receive 86,000 doses of the Pfizer/BioNTech vaccine for distribution to counties outside the city of Chicago, while Chicago will receive 23,000 doses, possibly as soon as December 13, shortly after the vaccine receives Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration. A key FDA committee is scheduled to meet to discuss the EUA on <u>December 10</u>. The state anticipates receiving further vaccine shipments each week thereafter, potentially hundreds of thousands of additional vaccine doses over the next few weeks. Dr. Ezike indicated that the vaccines will be stored in 20 ultra-cold storage units that IDPH has secured.

The State's initial vaccine allocation proposal would limit distribution to the 50 counties with the highest COVID-19 death rates per capita. Vaccine allocations would flow through Regional Hospital Coordinating Centers (RHCCs) in the 10 EMS regions outside Chicago (see an <u>IDPH</u> <u>RHCC map</u>). In those counties, hospitals selected by IDPH will receive an allocation for their

employees from the RHCCs. Due to limited vaccine supplies in the first distribution, hospitals slated to receive vaccine under the State's plan will need to prioritize which high-risk employees are to be vaccinated.

The Governor's PowerPoint presentation on the state's vaccine distribution plan can be viewed <u>here</u>, and a video replay of the Governor's press briefing can be viewed on Facebook at <u>https://www.facebook.com/GovPritzker/videos/3614582391989895</u>.

Stakeholders are getting a first chance to review the State's proposal today. IHA is reaching out to IDPH to clarify details of the plan, better understand the methodology for phase 1 distribution, and to clarify the impact on hospitals and healthcare workers in all regions of the state. IHA will continue to update members as more information becomes available.

Also today, IDPH held Office Hours for hospitals outside Chicago on the <u>I-CARE</u> enrollment process. A recording of the Office Hours should be available on Monday, and IHA will include a link to the recording in the Monday evening COVID-19 update. All hospitals are urged to quickly complete the I-CARE enrollment process and the provider agreement forms to ensure that they are eligible to receive vaccine allocations.

(Chicago has its own COVID-19 vaccine distribution system and plan, separate from the state. See Chicago's <u>COVID-19 vaccine website</u>.)

We also want to make you aware of two other important developments from the Illinois Department of Financial and Professional Regulation (IDFPR) and the U.S. Department of Health and Human Services (HHS) that have occurred within the past 24 hours in response to the COVID-19 pandemic.

IDFPR Issues COVID-19 Proclamations and Waivers

On Thursday, IDFPR issued several proclamations and waivers concerning licensure requirements/scope of practice as part of the state's response to the COVID-19 pandemic, many of which IHA has been advocating for. These actions cover:

- Modifying Licensure Requirements for Out-of-State Healthcare Workers to Practice in Illinois
- Variance for Inactive Respiratory Care Therapists
- Variance for Inactive Physician Assistants
- Variance for Inactive Nurses (LPNs, RPNs, APRNs)
- Variance for Inactive Physicians
- Scope of Practice for Pharmacists, Pharmacy Techs and Pharmacy Interns to Administer Flu and COVID Vaccines
- Modifying Scope of Practice for Dentists to Administer COVID Vaccines

For details, see an <u>IHA summary</u>. The proclamations and variances are posted on the <u>IDFPR</u> <u>website</u> (under Division of Professional Regulation/Health Care Professions, all dated December 3, 2020).

HHS Amends PREP Act Declaration re Liability and Telehealth

On Thursday, the HHS Secretary issued an amendment to his March 10, 2020 Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 ("PREP Act Declaration").

The PREP Act authorizes the Secretary of HHS to issue a declaration to provide liability protections to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of certain medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct," as defined in the PREP Act. Such declarations are subject to amendment as circumstances warrant.

Among other things, the <u>amendment ("Fourth Amendment")</u>:

- Authorizes healthcare personnel using telehealth to order or administer Covered Countermeasures, such as a diagnostic test that has received an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA), for patients in a state other than the state where the healthcare personnel are already permitted to practice. (While many states have decided to permit healthcare personnel in other states to provide telehealth services to patients within their borders, not all states have done so.)
- Provides an additional pathway to satisfy the Declaration's Limitations on Distribution section. Now Covered Persons have immunity under the PREP Act if they use on-label Covered Countermeasures licensed, approved, cleared, or authorized by the Food and Drug Administration (FDA) (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) to combat the COVID-19 public health emergency, without satisfying the Declaration's other Limitations on Distribution, such as having an agreement with the federal government.
- Provides a new pathway for immunity under the PREP Act for Covered Persons who use respiratory protective devices approved by NIOSH that the Secretary determines to be a priority for use to combat the COVID-19 public health emergency, without satisfying the Declaration's other restrictions, such as having an agreement with the federal government.
- Expands the scope of PREP Act immunity to cover potentially more healthcare providers who could administer COVID-19 and other vaccines by modifying and clarifying what CPR and other training is required for certain pharmacists, pharmacy interns, and pharmacy technicians to order or administer childhood or COVID-19 vaccines pursuant to the PREP Act declaration.
- Clarifies the scope of PREP Act immunity in various ways. For instance, the amendment makes explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections. The amendment also incorporates the HHS Office of the General Counsel's advisory opinions concerning the PREP Act and Declaration.

Click here for IHA's detailed summary of the amendment. Also see *HHS' press release*.

If you have questions or comments, please contact Tim Nuding, Senior Vice President, Member Services and Corporate Finance at 217-541-1164 or <u>tnuding@team-iha.org</u>.