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HHS and FDA Take Additional Measures to Aid Post-PHE Transition for Pharmacy Providers

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For the last three years, the federal government has taken considerable steps to aid providers in the fight against COVID-19. Although many of the waivers and flexibilities initiated in response to the pandemic have since expired or are in the process of being phased out, other federal agencies, including the Department of Health and Human Services ("HHS") and the Food & Drug Administration ("FDA") have taken new steps to aid the post-public health emergency ("PHE") transition.

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PREP Act Liability Immunity Extended Through 2024 for Pharmacists and Pharmacy Personnel

On May 9, 2023 the Secretary of HHS ("Secretary") issued the Eleventh Amendment to the Declaration Under the Public Readiness and Emergency Preparedness (PREP) Act for Medical Countermeasures Against COVID-19 (the "Amendment"). Crucially, the Amendment extends PREP Act liability immunity for pharmacists, pharmacy technicians and pharmacy interns through December 31, 2024, clearing up confusion among stakeholders as to the continued applicability of the PREP Act declarations in the waning hours of the federally-declared PHE which officially expired at 11:59 pm on May 11, 2023.

At the beginning of the COVID-19 pandemic in March of 2020, then-Secretary Alex Azar issued the initial declaration under the PREP Act approving certain medical countermeasures against COVID-19 ("Declaration"). As the battle against COVID-19 evolved, that initial Declaration was amended several times, adding new categories of qualified

providers, new COVID-19 countermeasures and revising the scope of prior amendments.

Many of those amendments to the Declaration expanded the scope of practice of pharmacists, pharmacy technicians, and pharmacy interns, permitting them to administer COVID-19 and influenza vaccines and other COVID-19 countermeasures irrespective of state laws to the contrary. When the official end of the public health emergency was announced, there was confusion as to whether the amendments under the PREP Act would also end.

In the latest Amendment, the Secretary makes clear that certain authorizations under the PREP Act will continue through December 31, 2024, acknowledging the end of the PHE while simultaneously noting that COVID-19 continues to present a risk for future public health emergencies. The provisions of the Amendment are intended to mitigate that risk.

Specifically, the Amendment, in relevant part, provides the following:

- Extends liability coverage for licensed pharmacists, pharmacy interns, and pharmacy technicians authorized to order and/or administer the "Covered Countermeasures" while they are authorized under an Emergency Use Authorization (EUA), when consistent with the terms of the EUA. This is intended to allay any concerns about liability risks arising from continued manufacturing, distribution, administration or use of Covered Countermeasures while they are authorized under an EUA.

- Recognizing the burden on healthcare providers caused by coterminous seasonal influenza infections and COVID-19 infections, the Amendment extends the time period of PREP Act coverage through December 31, 2024 to Qualified Persons who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, Covered Countermeasures that are COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests, in accordance with other requirements (e.g. CDC/ACIP and FDA authorizations).

To the extent that any state law would otherwise prohibit these healthcare professionals from prescribing, dispensing, or administering covered countermeasures that are COVID-19 vaccines, seasonal influenza vaccines or COVID-19 tests, such law is preempted.

Importantly, the Amendment made no changes to PREP Act immunity as it relates to pharmacists, pharmacy technicians, and pharmacy interns dispensing COVID-19 oral anti-viral treatments such as Paxlovid and Lagevrio, which is authorized under FDA authority. Additionally, the Amendment made no change to the "Test to Treat" program, which will continue to receive liability protection under the PREP Act.

The practical result of the Amendment is that patients will continue to have access to COVID-19 care. As noted in the Amendment, pharmacies are the most accessible health care providers, particularly in medically underserved areas.

Despite liability immunity, it remains crucial for pharmacists and pharmacy personnel to maintain accurate documentation of their activities during emergency response efforts. Documentation should include patient information, administration records, adverse

events, and any deviations from standard procedures. Compliance with state and federal regulations, such as reporting requirements for adverse events or medication errors, remains essential to ensure accountability and quality of care.

The extension of PREP Act liability immunity through 2024 brings clarity and extends legal protections for pharmacists and pharmacy personnel involved in the public health emergency response. By shielding them from liability, this extension enables pharmacists and pharmacy personnel to fulfill their roles with confidence and make informed decisions in the face of evolving challenges. However, it is important for pharmacists and pharmacy personnel to remember that adherence to standards of care should always guide their actions, even as they operate under the umbrella of liability immunity.

FDA Provides Exemptions from Certain DSCSA Requirements for Covered COVID-19 Products

On May 11, 2023, the FDA, using its authority under the Food, Drug, and Cosmetic Act (the "Act"), granted exemptions for covered COVID-19 products from certain requirements under the Drug Supply Chain Security Act (DSCSA). For purposes of the FDA's new exemptions, Covered COVID-19 products are "prescription drug products approved or authorized by the FDA to diagnose, cure, mitigate, treat, or prevent COVID-19." This includes vaccines and antivirals, among others.

The FDA issued these exemptions in response to the expiration of the PHE under Section 319 of the Public Health Service Act and its related COVID-19 DSCSA guidance that was implemented in the wake of the PHE. In an effort to avoid potential supply chain disruptions and aid manufacturers, wholesale distributors, repackagers, dispensers and their trading partners, the FDA determined that these new exemptions, many of which align with the FDA exemptions during the PHE, were needed.

Manufacturers

- The section 582(b)(1) product tracing requirements.
- The section 582(b)(2) product identifier requirements.
- The section 582(b)(4)(A)(i)(II) requirements to verify product at the package level using the product identifier and validate any applicable transaction history and transaction information in the manufacturer's possession for the purposes of a suspect product investigation, responding to an illegitimate product notification under section 582(b)(4)(B)(iii). However, manufacturers must still promptly conduct an investigation in coordination with trading partners as applicable and otherwise investigate the product to determine if it is illegitimate in accordance with section

582(b)(4)(A)(i)(II), and, upon determining such product is illegitimate, follow the requirements in section 582(b)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.

- The section 582(b)(4)(C) requirement that upon request from an authorized trading partner in possession or control of a product that it believes to be made by the manufacturer, such manufacturer verify the product using the product identifier. However, if the manufacturer has reason to believe the product is an illegitimate product, the manufacturer must still advise the person making the request of such belief at the time such manufacturer responds to the request for verification; the exemptions do not extend to this requirement.
- The section 582(b)(4)(E) requirement to verify the product identifier of a saleable returned product that is intended for further distribution.

Wholesale Distributors

- The 582(c)(1) product tracing requirements.
- The section 582(c)(2) product identifier requirements.
- The section 582(c)(4)(A)(i)(II) requirements to verify product at the package level using the product identifier and validate any applicable transaction history and transaction information in its possession for the purposes of a suspect product investigation or when responding to an illegitimate product notification under section 582(c)(4)(B)(iii). However, such wholesale distributors must still promptly conduct an investigation in coordination with trading partners as applicable and otherwise investigate the product to determine if it is illegitimate in accordance with section 582(c)(4)(A)(i)(II) and, upon determining such product is illegitimate, follow the requirements in section 582(c)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.
- The section 582(c)(4)(D) requirement to verify the product identifier of saleable returned product packaged without product identifiers that is intended for further distribution.

Dispensers

- The section 582(d)(1) product tracing requirements.
- The section 582(d)(2) product identifier requirements.
- The section 582(d)(4)(A)(ii)(II) requirement to verify a portion of suspect products at the package level using the product identifier], and section 582(d)(4)(A)(ii)(III) requirement to validate any applicable transaction history and transaction information in a dispenser's possession for the purpose of an investigation of suspect product under 582(d)(4)(A) or when responding to an illegitimate product notification under section 582(d)(4)(B)(iii). However, dispensers must still verify lot number in accordance with section 582(d)(4)(A)(ii)(I) and otherwise conduct an investigation the product to determine if it is illegitimate as required by section 582(d)(4)(A)(ii)(IV), and, upon determining such product is illegitimate, follow the requirements in section 582(d)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.

Repackagers

- The section 582(e)(1) product tracing requirements.
- The section 582(e)(2) product identifier requirements.
- The section 582(e)(4)(A)(i)(II) requirements to verify product at the package level using the product identifier] and validate any applicable transaction history and

transaction information in its possession for the purposes of a suspect product investigation, responding to an illegitimate product notification under section 582(e)(4)(B)(iii) or when prompted by a request for verification under 582(e)(4)(C). However, repackagers must still promptly conduct an investigation in coordination with trading partners as applicable and otherwise investigate the product to determine if it is illegitimate in accordance with section 582(e)(4)(A)(i)(II) and, upon determining such product is illegitimate, follow the requirements in section 582(e)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.

- The section 582(e)(4)(C) requirement that upon request from an authorized trading partner in possession or control of a product that it believes to be repackaged by the repackager, such repackager verify the product using the product identifier. However, if the repackager has reason to believe the product is an illegitimate product, the repackager must still advise the person making the request of such belief at the time such repackager responds to the request for verification; these exemptions do not extend to this requirement.
- The section 582(e)(4)(E) requirement to verify the product identifier of a saleable returned product that is intended for further distribution

In each case, the exemptions above apply only to covered COVID-19 products introduced by a manufacturer or repackager in a transaction into interstate commerce before November 27, 2024, and are effective until expiration of such product. Trading partners must continue to comply with all other applicable requirements of the DSCSA not identified in the new guidance.

Note, too, that the FDA encourages trading partners to communicate any such reliance on the new exemptions to its trading partners so as to not delay distribution. To the extent that compliance with the DSCSA does not present a barrier to distribution of covered COVID-19 products, the FDA encourages trading partners to continue complying with those exempted requirements.

The significant steps taken by HHS and the FDA will likely be welcomed by pharmacy providers who are emerging from a legal landscape that has been dramatically altered by the pandemic. Although we all are officially now living in the post-PHE world as of May 11, 2023, it is clear that the federal government is keeping a close eye as to how that transition unfolds. The healthcare attorneys at Dorsey & Whitney LLP will be doing the same.