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Ohio Provider Resource Association

MEMBER BRIEFING

FDA COMPLIANCE WHEN DISTRIBUTING PPE DURING THE COVID-19 PUBLIC HEALTH EMERGENCY

In light of the COVID-19 public health emergency, we are providing this information to members of the Ohio Provider Resource Association (OPRA) regarding compliance risks involved in distributing personal protective equipment (PPE) to employees, clients, and visitors. Below, we provide an overview of related issues for consideration, as well as high-level recommendations to potentially limit risk exposure. Guidance regarding creation and implementation of PPE policies (for example, when and where to require face masks) will be provided soon in a separate member briefing.

FDA Regulation of Face Masks and Other PPE

Nearly all PPE currently being worn to combat the spread of SARS-CoV-2, the virus that causes COVID-19, is regulated by the U.S. Food and Drug Administration (FDA). For example, face masks that are intended for "medical use," meaning (among other things) use in the treatment or prevention of disease, are considered to be "Class II" medical devices. Because FDA has taken the position that "medical use" includes use by the general public to prevent COVID-19 transmission, manufacturers and distributors of such face masks are technically subject to a variety of regulatory requirements. Generally, devices that do not meet these requirements would be deemed "adulterated" and/or "misbranded" by FDA, making their distribution – even without payment – unlawful. Importantly, developmental disabilities providers furnishing PPE to their own employees, clients, and/or visitors will be considered "distributors" under this FDA framework.

To help facilitate the availability of non-medical-grade PPE (such as cloth face masks) during the COVID-19 pandemic, FDA has issued emergency use authorizations (EUA), as well as various enforcement policies indicating that FDA has temporarily relaxed its approach and will not take action to enforce certain otherwise-applicable regulatory requirements so long as the PPE at issue does not "create an undue risk in light of the public health emergency."

Continuing with face masks as our example, the applicable enforcement policy states that FDA currently believes face masks do not "create an undue risk" so long as they are labeled in accordance with certain guidelines, specifically:

- The labeling must accurately describe the product as a face mask (not a "surgical mask" or "respirator");
- The labeling must include a list of the body-contacting materials, which must not include any drugs or biologics;
- The labeling must make recommendations that would reduce sufficiently the risk of use, including recommendations against use:
  - In any surgical setting or where significant exposure to liquid, bodily, or other hazardous fluids, may be expected;
  - In a clinical setting where the infection risk level through inhalation exposure is high; and
  - In the presence of a high intensity heat source or flammable gas; and
- The labeling must not suggest that the face mask is intended for:
  - Antimicrobial or antiviral protection;

- Infection prevention or reduction; or
- Particulate filtration.

FDA has published analogous guidance applicable to face shields, gloves, and hand sanitizer, among other items.

Practically, under the current circumstances, many providers may be distributing PPE about which they themselves may have minimal information. By doing so, a provider could be exposing itself to a wide range of potential FDA regulatory enforcement actions, ranging from warning letters to civil and criminal penalties. Notably, even a warning letter may have significant negative consequences for a provider, as such letters are made publically available online, and may (1) adversely impact a provider's reputation, and/or (2) help a private plaintiff establish the elements of another type of legal claim (e.g., negligence, misrepresentation, or the like).

To limit provider risk associated with distributing PPE to employees, clients, and/or other visitors, we recommend adhering to as many of FDA's recommendations as possible, particularly those related to product labeling. In many instances, FDA's labeling standards may be satisfied using a single-page information sheet, which may be distributed along with the PPE, posted in the provider's physical space, and/or posted on a provider's website (provided PPE recipients also receive instructions for accessing it). Even if it is not possible to comply fully with all applicable FDA standards (for example, because the specific body-contacting materials for a face mask are unknown), this strategy should, nonetheless, significantly reduce potential liability exposure because the dispositive question under FDA's current enforcement policies is *whether the product creates an undue risk* (not whether every stated condition is fully satisfied).

Importantly, the special EUAs and enforcement policies currently available from FDA are expressly limited to the duration of the federally declared COVID-19 public health emergency, and they are subject to change at any time as new public health concerns and priorities arise. The Vorys Health Care Team will continue monitoring for updates on these issues. Notably, we have also been helping clients in all industries prepare labeling sheets, purchase agreements, releases, and other risk-limiting documents related to PPE manufacturing, acquisition, use, and distribution. If there is anything we can do to assist you, please contact Suzanne Scrutton, Jolie Havens, Mairi Mull, or your regular Vorys attorney.

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