

JOHN BOYLE AND CHERYL MCKINNEY	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
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	:	
v.	:	
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JUDITH MEYER AND OSPTA @HOME., LLC D/B/A OSPTA HOME CARE & HOSPICE	:	No. 1212 WDA 2024
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	:	
Appellants	:	

Appeal from the Order Entered September 23, 2024  
In the Court of Common Pleas of Allegheny County Civil Division at  
No(s): No. GD-21-004147

BEFORE: McLAUGHLIN, J., LANE, J., and BENDER, P.J.E.

OPINION BY LANE, J.:

**FILED: September 9, 2025**

Judith Meyer ("Meyer") and OSPTA @HOME, LLC d/b/a OSPTA Home Care & Hospice ("OSPTA") (collectively, "Defendants") appeals from the order denying their motion for judgment on the pleadings in this personal injury action brought by John Boyle ("Boyle") and Cheryl McKinney ("McKinney") (collectively, "Plaintiffs"). We affirm.

On April 20, 2021, Plaintiffs commenced this action by filing a complaint in the trial court against Defendants, raising negligence claims related to an incident in which Meyer, a physical therapist employed by OSPTA, allegedly transmitted the COVID-19 virus to Plaintiffs.<sup>1</sup> The complaint averred as

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<sup>1</sup> For ease of reference, we refer to the SARS-CoV-2 virus that causes the COVID-19 disease as "the COVID-19 virus."

follows. At the time of the incident, Boyle was recovering from open-heart surgery at the home he shared with McKinney. Additionally, Plaintiffs were “both of an advanced age and suffer[ed] from various physical ailments.” Complaint, 4/20/21, at ¶ 13. As a result of the surgery, Boyle “was required to take physical therapy.” *Id.* at ¶ 15. “In order to reduce the likelihood of contact with any individuals outside of his residence” during the on-going COVID-19 pandemic, Boyle arranged for OSPTA to provide at-home physical therapy services. *Id.* at ¶ 16.

Meyer arrived at Plaintiffs’ home on November 8, 2020 “not wearing gloves, a face shield, or an appropriate face mask.” *Id.* at ¶¶ 17-18. Instead, Meyer “only had [on] a thin, disposable surgical mask.” *Id.* at ¶ 18. Meyer “immediately shook . . . Boyle’s hand, despite not having [on] gloves or other appropriate protective equipment.” *Id.* at ¶ 19. Meyer “did not wash her hands upon arrival or before performing physical therapy on” Boyle. *Id.* at ¶ 20.

Although Boyle arranged for Meyer to provide in-home physical therapy again on November 12, 2020, another OSPTA therapist provided the services instead. On November 14, 2020, OSPTA informed Plaintiffs that Meyer had tested positive for the COVID-19 virus. Within days, Plaintiffs “developed symptoms associated with COVID-19” and they “were both admitted to the hospital and were put on oxygen.” *Id.* at ¶¶ 25-27. Plaintiffs each spent approximately ten days in the hospital and, at the time of the filing of the

complaint, five months later, “continue[d] to suffer adverse effects associated with the disease.” **Id.** at ¶¶ 28-29.

Plaintiffs alleged that Meyer was negligent by: breaching her “duty to wear” proper personal protective equipment (“PPE”) and exposing Plaintiffs to an unreasonable risk of harm; “initiating skin-to-skin contact with” Boyle without wearing sufficient PPE; and providing physical therapy following known exposure to the COVID-19 virus. **Id.** at ¶¶ 32-34. Plaintiffs alleged that OSPTA was negligent under a respondeat superior theory. **See id.** at ¶¶ 39-42. In addition, they claimed that OSPTA failed: to properly train and supervise Meyer on the provision of at-home physical therapy during the pandemic; and to “provide adequate safeguards and screening of its employees” to prevent the spread of the virus. **See id.** at ¶ 44.

Defendants timely filed a notice of removal of the case to federal court. On December 20, 2021, the United States District Court for the Western District of Pennsylvania granted Plaintiffs’ motion to remand this case to the trial court. In doing so, the District Court found that the federal Public Readiness and Emergency Preparedness Act (“PREP Act”)<sup>2</sup> did not completely preempt Plaintiffs’ state-law negligence claims and therefore “the parties’ dispute regarding the applicability of the PREP Act as a potential defense of immunity must be resolved in state court.” **See Boyle v. Meyer**, 2021 WL 6051439, at \*\*3, 6 (W.D. Pa. 2021).

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<sup>2</sup> **See** 42 U.S.C. §§ 247d-6d, 247d-6e.

Following remand to the trial court, Defendants filed a joint answer and new matter. Defendants admitted that Meyer “was not wearing gloves or a face shield, but she was wearing a face mask.” Answer, 3/25/22, at ¶ 18. Defendants also admitted that Meyer did not wash her hands at Plaintiffs’ residence but averred that she washed her hands several times earlier in the day and applied hand sanitizer in her vehicle before entering Plaintiffs’ home. **See id.** at ¶ 20. Furthermore, Defendants asserted in their new matter that they are immune from liability pursuant to the PREP Act. **See** New Matter, 3/25/22, at ¶ 2. Plaintiffs filed a reply to the new matter.

On May 20, 2024, Defendants filed the instant motion for judgment on the pleadings, raising the immunity provisions of the PREP Act. Following briefing and oral argument, the trial court entered an order denying Defendants’ motion.<sup>3</sup> Defendants filed a timely notice of appeal. On December 17, 2024, the trial court filed an opinion explaining its reasons for the denial of Defendants’ motion pursuant to Pa.R.A.P. 1925(a).<sup>4</sup>

Defendants raise the following issue on appeal:

Whether the trial court erred in finding that a genuine issue of material fact precluding a grant of judgment on the pleadings based on PREP Act immunity, when it is undisputed that Defendants used and administered a countermeasure (a surgical

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<sup>3</sup> The order was dated September 18, 2024 and entered on the docket on September 20, 2024, but the trial court prothonotary did not provide notice of entry of the order pursuant to Pa.R.Civ.P. 236 until September 23, 2024.

<sup>4</sup> The trial court did not direct Defendants to file a Rule 1925(b) concise statement of errors complained of on appeal.

mask) covered by the PREP Act to prevent Plaintiffs from being infected with the COVID-19 virus?

Defendants' Brief at 2 (unnecessary capitalization omitted).

Before reaching the merits of this appeal, we must first address whether it is properly before this Court. Generally, an order denying a motion for judgment on the pleadings is interlocutory and not appealable. ***See All-Pak, Inc. v. Johnston***, 694 A.2d 347, 352-53 (Pa. Super. 1997) (quashing appeal from denial of motion for judgment on the pleadings as a non-final order under Pa.R.A.P. 341 and holding it is not an interlocutory order appealable as of right under Pa.R.A.P. 311). This Court *per curiam* directed Defendants to show cause why this appeal should not be quashed. In response, Defendants argued that the order is an appealable collateral order under Pa.R.A.P. 313, because the order involves the denial of a claim for immunity. This Court then discharged the rule to show cause order and referred the issue to the merits panel.

Upon review, we agree that the instant order is appealable under the collateral order doctrine. "[A]n order is collateral under Rule 313 if: (1) the order is separable from the underlying cause of action; (2) it involves a right too important to be denied review; and (3) it presents an issue that will be irreparably lost if appellate review is postponed until after final judgment." ***Brooks v. Ewing Cole, Inc.***, 259 A.3d 359, 371 (Pa. 2021) (holding orders denying summary judgment motion premised on sovereign immunity grounds were appealable collateral orders). We must construe the collateral order

doctrine narrowly to preserve the integrity of the final order rule and avoid piecemeal litigation. **See *McIlmail v. Archdiocese of Philadelphia***, 189 A.3d 1100, 1104 (Pa. Super. 2018); **see also** Pa.R.A.P. 341 (providing that generally, “an appeal may be taken as of right from any final order”).

We conclude that Defendants have satisfied each of the three collateral order elements. First, the question of Defendants’ immunity from suit — which turns on the interpretation of the PREP Act — is separate and distinct from the merits of Plaintiffs’ negligence claims, which implicate traditional Pennsylvania negligence principles. **See *Brooks***, 259 A.3d at 371-72 (holding that defendant’s claim of sovereign immunity was separable from underlying negligence action). Second, Defendants’ claim of federal statutory immunity from state negligence claims involves a right too important to be denied review. **See *id.*** at 372 (finding that resolution of legislative and constitutional sovereign immunity claim was too important to defer review as the right has “deeply rooted and far-reaching implications [that] outweigh the final judgment rule’s efficiency interests”). Finally, Defendants’ PREP Act immunity claim will be irreparably lost if postponed until after final judgment because, to the extent Defendants’ present appellate claims are meritorious, they would be entirely immune from the instant lawsuit. **See *id.*** at 372-73 (concluding that sovereign immunity claim would be irreparably lost if deferred because “the protection [of immunity] is from a lawsuit itself not simply a mere shield from judgment or liability”). As we find that the order denying Defendants’

motion for judgment on the pleadings was an appealable collateral order, we proceed to reach the merits of their appeal.

Our standard of review of a ruling on a motion for judgment on the pleadings is *de novo*, and our scope of review is plenary. ***See SpiriTrust Lutheran v. Wagman Constr., Inc.***, 314 A.3d 894, 904 (Pa. Super. 2024). A motion for judgment on the pleadings is similar to a demurrer. ***See Washabaugh v. Gaudenzia, Inc.***, 316 A.3d 1008, 1011 (Pa. Super. 2024). “Judgment on the pleadings is proper only where the pleadings evidence that there are no material facts in dispute such that a trial by jury would be unnecessary.” ***Five Star Bank v. Chipego***, 312 A.3d 910, 918 (Pa. Super. 2024) (citation omitted).

Like the trial court, we “must accept as true all well pleaded statements of fact, admissions, and any documents properly attached to the pleadings presented by the party against whom the motion is filed, considering only those facts which were specifically admitted.” ***Washabaugh***, 316 A.3d at 1011. Grant of a motion for judgment on the pleadings is proper “only when the moving party’s right to succeed is certain and the case is so free from doubt that the trial would clearly be a fruitless exercise.” ***Id.*** (citation omitted).

In 2005, Congress enacted the PREP Act to “encourage the expeditious development and deployment of medical countermeasures during a public

health emergency.” **Cannon v. Watermark Ret. Communities, Inc.**, 45 F.4th 137, 139 (D.C. Cir. 2022) (citation omitted).<sup>5</sup>

. . . The PREP Act protects certain covered individuals — such as pharmacies and drug manufacturers — from lawsuits during a public-health emergency. The Act lies dormant until invoked by the Secretary of . . . Health and Human Services [“Secretary”]. If the Secretary deems a health threat a public-health emergency, he may publish a declaration in the Federal Register recommending certain “covered countermeasures.” When the Secretary makes such a declaration, the covered individuals become immune from suit and liability from claims related to the administration of a covered countermeasure.

**Estate of Maglioli v. Alliance HC Holdings LLC**, 16 F.4th 393, 400-01 (3d Cir. 2021) (*quoting* 42 U.S.C. § 47d-6d(b)(1)).<sup>6</sup>

The immunity provision of the PREP Act provides:

Subject to the other provisions of this section, a **covered person** shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a **covered countermeasure** if a declaration [of public health emergency] has been issued [by the Secretary] with respect to such countermeasure.

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<sup>5</sup> While not binding, we find the federal Court of Appeals and District Court decisions discussed herein persuasive in interpreting the PREP Act. **See Cole v. Pennsylvania Dep’t of Env’tl. Prot.**, 329 A.3d 1228, 1236 n.30 (Pa. 2025) (stating that “lower federal courts’ interpretations of federal law have only persuasive value in” Pennsylvania courts).

<sup>6</sup> To counteract the effect of the PREP Act immunity provision, which “cuts off forms of relief that might otherwise have been available to people harmed by diagnostics, treatments, or vaccines,” the PREP Act “also established a ‘Covered Countermeasure Process Fund’ to compensate for such harms.” **Cannon**, 45 F.4th at 139 (*citing* 42 U.S.C. § 247d-6e(a)(1)).



42 U.S.C. § 247d-6d(a)(1) (emphases added). This immunity provision “applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure . . . .”

42 U.S.C. § 247d-6d(a)(2)(B).

The PREP Act defines the terms “covered person” and “covered countermeasure,” which limit the scope of the immunity provision. **See Cannon**, 45 F.4th at 139 (explaining that “[a] court should deny [PREP Act] immunity if, for example, the defendant is not a covered person, the measure administered is not covered, or the claim otherwise falls beyond the scope of the Secretary’s declaration”). A “covered person” includes:

- (i) a manufacturer of [a covered] countermeasure;
- (ii) a distributor of such countermeasure;
- (iii) a **program planner** of such countermeasure;
- (iv) a **qualified person** who prescribed, administered, or dispensed such countermeasure; or
- (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

42 U.S.C. § 247d-6d(i)(2)(B)(i)-(v) (emphases added). A “program planner” is defined as a person:

. . . who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a [public health emergency] declaration . . . .

42 U.S.C. § 247d-6d(i)(6). A “qualified person” means

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense [covered] countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a [public health emergency] declaration by the Secretary . . . .

42 U.S.C. § 247d-6d(i)(8).

The PREP Act defines a “covered countermeasure” to include a “qualified pandemic or epidemic product,” “a security countermeasure,” a drug or biological product approved for emergency use, and “a respiratory protective device” approved by the National Institute for Occupational Safety and Health.

42 U.S.C. § 247d-6d(i)(1). As relevant here, a “covered countermeasure” also includes a “device (as such term is defined [in] the Federal Food, Drug and Cosmetic Act [(“FD&C Act”)] that is authorized for emergency use in accordance with section 564, 564A, or 564B of the” FD&C Act. 42 U.S.C. § 247d-6d(i)(1)(C).

On March 17, 2020, the Secretary declared COVID-19 a public health emergency under the PREP Act. **See** Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020).<sup>7</sup> Since that date, the Secretary amended the public health emergency

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<sup>7</sup> We take judicial notice of the public health emergency declaration, as well as the emergency use authorizations discussed *infra*. **See** 42 Pa.C.S.A. § 5327(b) (providing that when “determining the law of any jurisdiction or governmental unit thereof outside this Commonwealth, the tribunal may (Footnote Continued Next Page)

declaration on multiple occasions to clarify the extent of the public health emergency and PREP Act immunity. **See, e.g.**, Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21012 (Apr. 15, 2020).

On April 24, 2020, the United States Food and Drug Administration (“FDA”) issued an emergency use authorization (“EUA”) to permit “the use of face masks” by members of the general public and health care personnel in healthcare settings “as source control” to prevent the spread of the COVID-19 virus. FDA Face Mask EUA Letter, at 3 (Apr. 24, 2020), *available at*

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consider any relevant material or source, . . . whether or not submitted by a party or admissible under the rules of evidence”); **see also Sch. Express, Inc. v. Upper Adams Sch. Dist.**, 303 A.3d 186, 195-96 (Pa. Cmwlth. 2023) (holding trial court properly took judicial notice of enactment of COVID-19 school closure legislation and Governor’s school closure executive orders when considering motion for judgment on the pleadings); **Ruff v. York Hosp.**, 257 A.3d 43, 60 n.7 (Pa. Super. 2021) (providing while “[t]his Court is not bound by decisions of the Commonwealth Court[,]” we may rely on its decisions as persuasive authority).

However, we decline to take notice of, or consider, the Department of Health and Human Services (“HHS”) advisory opinions upon which Defendants rely. **See** Motion for Judgment on the Pleadings, 5/20/24, Exhibits B-16 to B-21; **see also** Defendants’ Reply Brief, Addendum B. As the Court of Appeals for the Third Circuit has explained, the PREP Act “does not empower the Secretary to regulate the scope of the judicial power vested by the statute.” **Estate of Maglioli**, 16 F.4th at 403 (citation omitted). Accordingly, “[d]eference is not owed to [the advisory opinions] for the simple reason that HHS is not delegated authority under the PREP Act to interpret the scope of” the statute’s immunity provisions. **Id.** (declining to afford deference to HHS advisory opinions and statements in emergency declaration amendments that the PREP Act operates as a complete preemption of state law); **see also Martin v. Petersen Health Operations, LLC**, 37 F.4th 1210, 1214 (7th Cir. 2022) (same).

<https://www.fda.gov/media/137121/download?attachment> (last accessed Aug. 12, 2025). The EUA applied to “single or multiple use[]” masks and “cloth face coverings” but specifically exempted “[s]urgical masks.” **Id.** at 1 n. 1, 2. The EUA additionally provided that the authorized facemasks “are not intended to be used as PPE” and imposed labeling requirements on authorized facemasks, including “recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high.” **Id.** at 3-4.

“On August 5, 2020, the [FDA] granted [EUA] for disposable, single-use surgical masks . . . for use in healthcare settings by healthcare personnel” as PPE to prevent the spread of COVID-19. FDA Surgical Mask EUA Letter, at 1 (Mar. 6, 2023), *available at* <https://www.fda.gov/media/140894/download?attachment> (last accessed Aug. 12, 2025). The surgical mask-EUA did not include all single-use surgical masks, however, as it only applied to masks which met certain “performance criteria,” such as fluid resistance and particulate filtration requirements. **See id.** at 2-4. Over time, the FDA added surgical masks (identified by product name and manufacturer) to the approved list of surgical masks, which appeared in Appendix A of the EUA. **See id.** at Appendix A. On March 6, 2023, the FDA withdrew the August 5, 2020 surgical mask-EUA and reissued it in its entirety but removed the eligibility criteria such that no additional masks could be added to Appendix A. **See id.** at 2 & n.9.

On appeal, Defendants argue that the trial court erred by not finding that the PREP Act bars Plaintiffs’ negligence claims; Defendants assert that

they met each of the four requirements of the statutory immunity provision. First, Defendants note that on March 17, 2020, the Secretary declared a public health emergency, triggering PREP Act immunity related to COVID-19 countermeasures. Second, Defendants aver that they are “covered person[s]” under the statute, as they fall within both the “program planner” and “qualified person” categories of the statutory definition. 42 U.S.C. § 247d-6d(a)(1), (i)(2)(B)(iii)-(iv), (6), (8). Defendants contend that a “program planner” broadly includes any “person or entity, like . . . OSPTA [or Meyer, an OSPTA employee], who develops a program to reduce the spread of COVID[-19].” Defendants’ Brief at 20. Defendants were also “qualified person[s]” “because they are healthcare providers authorized to administer and/or use FDA approved medical devices, such as face masks, to prevent or mitigate the spread of COVID[-19].” **Id.** at 21.

Third, Defendants contend that Plaintiffs’ complaint on its face alleges that Meyer utilized a “covered countermeasure,” the “thin, disposable surgical mask” Meyer was wearing when she performed physical therapy on Boyle. 42 U.S.C. § 247d-6d(a)(1); **see also** Complaint, 4/20/21, at ¶ 18. Defendants assert that Meyer’s surgical mask constituted a “device” approved for emergency use by the FDA, as required under the PREP Act. **See** 42 U.S.C. § 247d-6d(i)(1)(C).

Fourth, Defendants argue that Meyer’s use of a covered countermeasure bears a “causal relationship” with Plaintiffs’ “claim for loss” based on their COVID-19 illness. 42 U.S.C. § 247d-6d(a)(2)(B). Defendants contend that

the PREP Act establishes a liberal causation standard to invoke immunity, requiring only that a covered countermeasure has “played some role in bringing about or contributing to the plaintiff’s injury.” Defendant’s Brief at 24 (*quoting Hampton v. California*, 83 F.4th 754, 764 (9th Cir. 2023)). According to Defendants, Plaintiffs’ allegation that Meyer wore a surgical mask while treating Boyle demonstrated that a covered countermeasure played a role in bringing about Plaintiffs’ injuries.

Defendants argue that the trial court erred by taking an “overly restrictive” view of PREP Act immunity by focusing on Plaintiffs’ allegations concerning “countermeasures not taken,” such as Meyer’s alleged failure to wash her hands or wear gloves or a face shield, rather than the undisputed fact that she wore a surgical mask when treating Boyle. Defendants’ Brief at 12-13. Defendants aver that Plaintiffs’ allegations that Meyer could have employed “different type[s] of countermeasure[s] that may have been more effective at preventing infection” are “immaterial as a matter of law” under the PREP Act. *Id.* at 28 (emphasis omitted). Instead, Defendants asserts that, exactly because Plaintiffs allege that “Meyer used the wrong covered countermeasure,” their claims have “the necessary ‘causal connection’ between the injury and the use of a covered countermeasure” to trigger PREP Act immunity. *Id.* at 33.

Defendants rely on *Maney v. Brown*, 91 F.4th 1296 (9th Cir. 2024). In *Maney*, inmates sued government officials in federal court over their decision to prioritize prison staff for the receipt of the COVID-19 vaccine over

the inmates. **See id.** at 1298-99. The District Court denied the officials' motion to dismiss based on the PREP Act, and the officials appealed. **See id.** at 1299. The Court of Appeals reversed, finding that the PREP Act immunized claims related to the vaccine prioritization scheme at issue in the case, which it determined was a "policy-level" decision to not administer a covered countermeasure. **Id.** at 1301. In arriving at this conclusion, the **Maney** court found that the PREP Act had "a sweeping statutory reach" "to extend immunity to persons who make policy-level decisions regarding administration or use of covered countermeasures and do not directly administer countermeasures to particular individuals." **Id.** at 1301-02 (citation omitted).

Defendants argue that "**Maney** is instructive" and that the trial court "misunderstood the proper context of the term 'administration' as set forth in the PREP Act." Defendants' Brief at 30. Applying the lessons of **Maney** to the present case, Defendants maintain that their "[d]ecision making as to which countermeasures to use [when treating Boyle], *i.e.*, which mask or other countermeasure should be used . . . goes . . . to 'administration' of a covered countermeasure." **Id.** Defendants assert that, because the trial court failed to recognize that PREP Act protected their "good[-]faith" efforts "to protect their patients from the COVID[-19] virus," this Court must reverse the trial court's denial of their motion for judgment on the pleadings. **Id.** at 37.

In its opinion, the trial court explained that it denied Defendants' motion for judgment on the pleadings based on "the absence of a causal connection" between Defendants' use of a covered countermeasure and Plaintiffs' injuries.

Trial Court Opinion, 12/17/24, at 12. The court reasoned that PREP Act immunity only “applies to claims involving action, *i.e.* the administration or use of covered countermeasures,” while “[c]laims of nonuse or inaction are excluded from the PREP Act.” ***Id.*** The court concluded that in this matter, Plaintiffs have “not claimed that the administration or use of a countermeasure resulted in the harm” but instead that “the failure to utilize a countermeasure or inaction led to the injury.” ***Id.*** The court found that:

. . . Plaintiff[s’ allegations that Defendants] failed to implement or properly execute [proper] safety measures or protocols related to the COVID-19 pandemic . . . do not amount to the administration of countermeasures under the PREP Act. . . . The complaint does not allege that [Defendants] failed to properly administer vaccines, biological agents, drugs, or devices, which would have triggered the PREP Act’s immunity provisions, but rather that [D]efendants negligently failed to protect Plaintiffs from contracting the disease due [to Defendants’ failure to use] PPE[] and [they] otherwise violated the standard of care in [their] treatment of [Boyle].

***Id.*** at 9. The court explained that Defendants’ arguments to the contrary that Meyer “was implementing countermeasures” while treating Boyle merely shows that a genuine dispute of material facts existed warranting denial of the motion for judgment on the pleadings. ***Id.*** at 13.

Based on our review, we find no error in the trial court’s denial of Defendants’ motion for judgment on the pleadings. ***See SpiriTrust Lutheran***, 314 A.3d at 904. In undertaking our review, we reiterate that, like the trial court, our review is confined to the well-pleaded allegations of the



complaint and Defendants' admissions.<sup>8</sup> **See Washabaugh**, 316 A.3d at 1011. Moreover, a court may only grant judgment on the pleadings when there is no dispute about a material fact such that the moving party's success on the merits is certain. **See id.**; **see also Five Star Bank**, 312 A.3d at 918.

Here, there are several disputed facts that prevent the grant of judgment in favor of Defendants.<sup>9</sup> First, it is unclear on the pleadings whether Meyer's "thin, disposable surgical mask" was a covered countermeasure under the PREP Act. 42 U.S.C. § 247d-6d(a)(1); **see also** Complaint, 4/20/21, at ¶ 18. The FDA's April 24, 2020 EUA established that certain "single or multiple use[]" "face masks" constituted covered countermeasures under the PREP Act, as "device[s] . . . authorized for emergency use in accordance with" the FD&C Act. 42 U.S.C. § 247d-6d(i)(1)(C); **see also** FDA Face Mask EUA Letter, at 3 (Apr. 24, 2020). However, the April 24, 2024 EUA only applied to face masks that met certain labeling requirements and entirely excluded surgical masks. **See** FDA Face Mask EUA Letter, at 3-4 & n.2 (Apr. 24, 2020). The subsequent August 5, 2020 EUA applied to surgical masks but only designated masks that

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<sup>8</sup> Although a court deciding a motion for judgment on the pleadings may also consider documents attached to the non-moving party's pleadings, Plaintiffs did not attach any documents to their complaint or reply to Defendants' new matter. **See Washabaugh**, 316 A.3d at 1011.

<sup>9</sup> While the trial court did not reach whether Meyer's surgical mask was a covered countermeasure or whether Defendants were covered persons, Plaintiffs opposed Defendants' motion for judgment on the pleadings on those grounds. Furthermore, we may affirm the trial court's order on any basis supported by the record. **See O'Brien v. Beatty**, 329 A.3d 685, 690 n.3 (Pa. Super. 2024).

met certain performance specifications and that appeared in Appendix A of the EUA. **See** FDA Surgical Mask EUA Letter, at 1-4, Appendix A (Mar. 6, 2023). Thus, based simply on the complaint's allegation that Meyer wore a "thin, disposable surgical mask," we are unable to determine whether the mask met the requirements of either EUA. Complaint, 4/20/21, at ¶ 18.<sup>10</sup>

Second, the pleadings do not conclusively establish that Defendants are covered persons under the PREP Act. Defendants argue that they fall under the "program planner" or "qualified person" definitions of a covered person. Each of these definitions requires that the individual in question had authority over the administration or use of a covered countermeasure. **See** 42 U.S.C. § 247d-6d(i)(6) (defining a "program planner" as a person who, *inter alia*, supervised or administered a program involving the use of a covered countermeasure or who "provide[d] a facility to administer or use a covered countermeasure"), (8)(A) (defining a "qualified person" as a health professional or other individual who prescribes, administered, or dispensed a covered countermeasure in a state in which they have the authority to do

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<sup>10</sup> Indeed, the confusion regarding which EUA, if any, applied to Meyer's surgical mask is evident in Defendants' motion and briefing, as they relied solely on the April 24, 2024 EUA in their motion for judgment on the pleadings and initial appellate brief and raised the August 5, 2020 EUA for the first time in their reply brief. **See** Motion for Judgment on the Pleadings, 5/20/24, at ¶¶ 63-65, Exhibit C; **see also** Defendants' Brief at 23; Defendant's Reply Brief at 10-11, Addendum A.

so).<sup>11</sup> Yet, as noted above, it remains in dispute whether Meyer's surgical mask — the only covered countermeasure raised in the pleadings — met the statutory definition. Therefore, at this juncture of the proceedings, it is unclear whether Defendants are covered persons under the PREP Act. While development of the factual record in this case may bear out that Defendants are in fact covered persons, the pleadings alone do not resolve this question.

Finally, even if the pleadings indisputably established that Defendants are covered persons and the surgical mask Meyer wore while treating Boyle was a covered countermeasure, we agree with the trial court that judgment on the pleadings was not appropriate. The overwhelming consensus within the federal courts is that "the PREP Act provides immunity only from claims that relate to 'the administration to or the use by an individual of' a covered countermeasure — not such a measure's **non**-administration or **non**-use." *Hampton*, 83 F.4th at 764 (citation omitted and emphasis in original); **see also, e.g., Martin**, 37 F.4th at 1213-14 (concluding that claims concerning nursing home's staffing levels, allowing sick nurses to continue working, failure to isolate infected patients, and failure to provide sufficient PPE were "the opposite of a contention that a covered countermeasure caused harm" and thus were "not even arguably preempted" by the PREP Act); **Testa v.**

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<sup>11</sup> A program planner also includes an individual "within a category of persons so identified in a declaration by the Secretary." 42 U.S.C. § 247d-6d(i)(8)(B). Defendants have not cited a declaration that identified them as program planners.

***Broomall Operating Co., L.P.***, 622 F.Supp.3d 4, 10 (E.D. Pa. 2022) (stating that District Courts in the Third Circuit “have resoundingly found that the PREP Act does not shield a covered individual from claims arising out of its failure to administer or use a covered countermeasure”). While ***Maney*** found that immunity attached to a prison’s “policy-level” failure to administer a covered countermeasure, the COVID-19 vaccine, the court recognized that the case stood as an exception to the general rule that the PREP Act does not apply to non-administration or non-use of a countermeasure, as it involved the “prioritization of a scarce countermeasure.” ***Maney***, 91 F.4th at 1301.

Additionally, the mere fact that a defendant used a covered countermeasure in a manner unrelated to the claims at issue is insufficient grounds to invoke PREP Act immunity. The Court of Appeals for the Ninth Circuit has stated:

At the very least, . . . for PREP Act immunity to apply, the underlying use or administration of a covered countermeasure must have played some role in bringing about or contributing to the plaintiff’s injury. It is not enough that some countermeasure’s use could be described as relating to the events underpinning the claim in some broad sense.

***Hampton***, 83 F.4th at 764-65 (footnote omitted) (holding, in action challenging transfer of COVID-19-infected inmates into prison leading to another inmate’s death, that provision of COVID-19 tests — a covered countermeasure — to transferred inmates did not immunize prison officials because complaint did “not describe a causal relationship between the administration of . . . the tests and [the decedent’s] death”); ***see also Brown***

**v. Big Blue Healthcare, Inc.**, 480 F.Supp.3d 1196, 1206 & n.13 (D. Kan. 2020) (holding that allegation in complaint that defendant used diagnostic tests — a covered countermeasure — in its facility was not “sufficient to invoke the PREP Act as to all claims that arise in that facility” because the plaintiff did “not tie the claim of loss to the administration or use of those tests”).

Here, Plaintiffs alleged that Meyer was negligent based on her failure to wear gloves, not washing her hands at Plaintiffs’ home, shaking Boyle’s hand upon arrival, and touching numerous objects in the home. **See** Complaint, 4/20/21, at ¶¶ 18-21. Plaintiffs further averred OSPTA was negligent for failing to screen its employees for the COVID-19 virus or properly train or supervise employees in providing physical therapy during the pandemic. **See id.** at ¶ 44. Plainly, these allegations do not relate to Defendants’ use or administration of a covered countermeasure, but rather to Meyer’s **failure** to wear proper PPE and maintain sanitary conditions, as well as OSPTA’s **failure** to screen, train, and supervise its employees. As such, they fall outside the class of state-law claims preempted by the PREP Act. **See Hampton**, 83 F.4th at 764. While **Maney** found that immunity attaches to certain “failure-to-administer claims,” the present case does not involve the provision of a scarce countermeasure that would trigger the exception to the general rule that claims involving the non-use and non-administration of countermeasures do not fall under the PREP Act. **See Maney**, 91 F.4th at 1301.

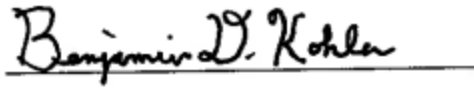
Furthermore, Plaintiffs’ claims are sufficiently unrelated to Meyer wearing a surgical mask to evade PREP Act immunity, as they allege

negligence based upon Meyer's and Defendant's failure to take additional actions beyond the mask she had on when she treated Boyle. **See Hampton**, 83 F.4th at 764. We note only one exception to our holding as it appears that Plaintiffs' allegations that Meyer failed to wear "a face shield[] or an appropriate face mask" relates to the same purpose as a surgical mask, *i.e.* to prevent the airborne transmission of the COVID-19 virus. Complaint, 4/20/21, at ¶ 18. However, it is premature on the present record to ascertain whether Defendants are immune from a claim that Meyer was negligent based upon her decision to wear a disposable surgical mask instead of a different kind of mask or face shield. Instead, we leave that determination to the trial court, following the development of the factual record regarding whether Meyer's mask was in fact a covered countermeasure.

Accordingly, we conclude, in light of the pleadings filed in this particular matter, that the trial court properly found that material facts remain in dispute regarding the application of PREP Act immunity to Plaintiffs' claims. **See Five Star Bank**, 312 A.3d at 918. We therefore affirm the court's denial of Defendants' motion for judgment on the pleadings and remand for further proceedings.

Order affirmed. Case remanded. Jurisdiction relinquished.

Judgment Entered.

A handwritten signature in cursive script, reading "Benjamin D. Kohler", is written over a horizontal line.

Benjamin D. Kohler, Esq.  
Prothonotary

9/9/2025