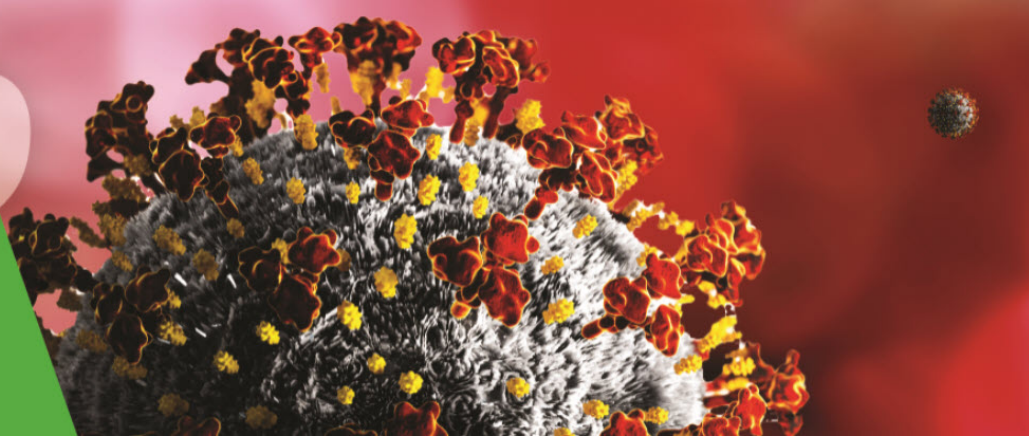


COVID-19

**SPECIAL EDITION
PANDEMIC RESPONSE**



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A ProAssurance Company

**One Year Later:
The PREP Act
and
COVID-19**

March 18, 2021

Brief Overview of PREP Act

- ▶ The Public Readiness and Emergency Preparedness Act (“PREP” Act).
- ▶ The PREP Act provides liability immunity to a large group of entities and individuals for the manufacture, distribution, prescription, and use of drugs, biological products, or devices meant to combat a pandemic.
- ▶ 42 U.S.C. § 247d-6d and 6e.

Declaration and Seven Amendments

- ▶ *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 15198-01 (Mar. 10, 2020, published Mar. 17, 2020).
 - ▶ *Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 21012-02 (Apr. 10, 2020, published Apr. 15, 2020);
 - ▶ *Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 35100-01 (June 4, 2020, published June 8, 2020);
 - ▶ *Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 52136-01 (Aug. 19, 2020, published Aug. 24, 2020);
 - ▶ *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*, 85 FR 79190-01 (Dec. 3, 2020, published 9, 2020);
 - ▶ *Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 7872-02 (Jan. 28, 2021, published Feb. 2, 2021);
 - ▶ *Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 9516-01 (Feb. 11, 2021, published Feb. 16, 2021); and
 - ▶ *Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 14462-02 (Mar. 11, 2021, published Mar. 16, 2021).

Six Advisory Opinions

- *Advisory Opinion on the PREP Act Declaration* (Apr. 17, 2020, as modified on May 19, 2020);
- *Advisory Opinion 20-02 on the PREP Act Declaration* (May 19, 2020);
- *Advisory Opinion 20-03 on the PREP Act Declaration* (Oct. 23, 2020);
- *Advisory Opinion 20-04 on the PREP Act Declaration* (Oct. 23, 2020);
- *Advisory Opinion 21-01 on the PREP Act Declaration* (Jan. 8, 2020); and
- *Advisory Opinion 21-02 on the PREP Act Declaration* (Jan. 12, 2021).

Available at <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

Case Law on Nursing Home PREP Act COVID Litigation



- ▶ *McCalebb v. AG Lynwood, LLC*, No. 2:20-CV-09746-SB-PVC, 2021 WL 911951 (C.D. Cal. Mar. 1, 2021).
- ▶ *Robertson v. Big Blue Healthcare, Inc.*, No. 220CV02561HLTTJJ, 2021 WL 764566 (D. Kan. Feb. 26, 2021);
- ▶ *Saunders v. Big Blue Healthcare, Inc.*, No. 220CV02608HLTTJJ, 2021 WL 764567 (D. Kan. Feb. 26, 2021);
- ▶ *Garcia v. Welltower*, No. SACV2002250JVSKESEX, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021);
- ▶ *Lyons v. Cucumber Holdings, LLC*, No. CV2010571JFWJPRX, 2021 WL 364640 (C.D. Cal. Feb. 3, 2021);
- ▶ *Dupervil v. All. Health Operations, LCC*, No. 20CV4042PKCPK, 2021 WL 355137 (E.D.N.Y. Feb. 2, 2021);
- ▶ *Grohmann v. HCP Prairie Vill. KS OPCO LLC*, No. 20-2304-DDC-JPO, 2021 WL 308550 (D. Kan. Jan. 29, 2021);
- ▶ *Goldblatt v. HCP Prairie Vill. KS Opco LLC*, No. 20-2489-DDC-KGG, 2021 WL 308158 (D. Kan. Jan. 29, 2021);
- ▶ *Anson v. HCP Prairie Vill. KS OPCO LLC*, No. 20-2346-DDC-JPO, 2021 WL 308156 (D. Kan. Jan. 29, 2021);
- ▶ *Hatcher v. HCP Prairie Vill. KS OPCO LLC*, No. 20-2374-SAC-JPO, 2021 WL 733326 (D. Kan. Jan. 27, 2021);
- ▶ *Estate of Smith by & through Smith v. Bristol at Tampa Rehab. & Nursing Ctr., LLC*, No. 8:20-CV-2798-T-60SPF, 2021 WL 100376 (M.D. Fla. Jan. 12, 2021);
- ▶ *Parker through Parker v. St. Jude Operating Co.*, LLC, No. 3:20-CV-01325-HZ, 2020 WL 8362407 (D. Or. Dec. 28, 2020);
- ▶ *Gunter v. CCRRC OPCO-Freedom Square, LLC*, No. 8:20-CV-1546-T-36TGW, 2020 WL 8461513 (M.D. Fla. Oct. 29, 2020);
- ▶ *Saldana v. Glenhaven Healthcare LLC*, No. CV205631FMOMAAX, 2020 WL 6713995 (C.D. Cal. Oct. 14, 2020);
- ▶ *Sherod v. Comprehensive Healthcare Mgmt. Servs.*, LLC, No. 20CV1198, 2020 WL 6140474 (W.D. Pa. Oct. 16, 2020);
- ▶ *Martin v. Serrano Post Acute LLC*, No. CV 20-5937 DSF (SKX), 2020 WL 5422949 (C.D. Cal. Sept. 10, 2020);
- ▶ *Fortune v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2318-HLT-JPO, 2020 WL 4815097 (D. Kan. Aug. 19, 2020);
- ▶ *Rodina v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2319-HLT-JPO, 2020 WL 4815102 (D. Kan. Aug. 19, 2020);
- ▶ *Lutz v. Big Blue Healthcare, Inc.*, 480 F. Supp.3d 1207 (D. Kan. Aug. 19, 2020);
- ▶ *Campbell v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2265-HLT-JPO, 2020 WL 4815082 (D. Kan. Aug. 19, 2020);
- ▶ *Eaton v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2291- HLT-JPO, 2020 WL 4815085 (D. Kan. Aug. 19, 2020);
- ▶ *Long v. Big Blue Healthcare, Inc.*, No. 2:20-CV- 2263-HLT-JPO, 2020 WL 4815079 (D. Kan. Aug. 19, 2020);
- ▶ *Jackson v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2259-HLT-JPO, 2020 WL 4815099 (D. Kan. Aug. 19, 2020);
- ▶ *Brown v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2261-HLT-JPO, 2020 WL 4815078 (D. Kan. Aug. 19, 2020);
- ▶ *Block v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2262-HLT-JPO, 2020 WL 4815076 (D. Kan. Aug. 19, 2020);
- ▶ *Baskin v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2267-HLT-JPO, 2020 WL 4815074 (D. Kan. Aug. 19, 2020);
- ▶ *Harris v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2266-HLT-JPO, 2020 WL 4815098 (D. Kan. Aug. 19, 2020); and
- ▶ *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp.3d 518 (D.N.J. Aug. 12, 2020).

Case Law on Product Liability PREP Act COVID Litigation



Case Law on (non-Nursing Home) Med Mal PREP Act COVID Litigation



Case Law on Wage Claim PREP Act COVID Litigation



▶ *Haro v. Kaiser Found. Hosps.*, No. CV 20-6006-GW-JCX, 2020 WL 5291014 (C.D. Cal. Sept. 3, 2020).

The Big Question:

- So, are we out of the woods?
- Or, are we waiting for the other shoe to drop?

➤ Covered Person

- ▶ Manufacturers and Distributors
- ▶ Providers (“qualified persons”)
- ▶ Governmental and related entities (“program planners”)

➤ Covered Countermeasure

- ▶ Approved/Cleared/Licensed Products
- ▶ Investigational Products
- ▶ Emergency Use Authorization (EUA) Products

➤ Willful Misconduct

The Covered Countermeasure Process Fund

- ▶ Since its inception in 2010 :
 - ▶ 551 claims for all of the various public health emergencies.
 - ▶ 450 of those claims were ineligible for compensation.
 - ▶ 62 of those claims of those claims are currently in the medical review process.
 - ▶ 39 of those claims were eligible for compensation.
 - Of the 39 claims eligible for compensation:
 - > 10 of the claims did not have any compensable expenses or losses.
 - > 29 claims were compensable.
 - ▶ Total payments for 29 claims has been more than \$6 million.

Available at <https://www.hrsa.gov/cicp/cicp-data> (last visited on Mar. 1, 2021).

The Seven Amendments to the Declaration

- ▶ *Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 21012-02 (Apr. 10, 2020, published Apr. 15, 2020);
- ▶ *Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 35100-01 (June 4, 2020, published June 8, 2020);
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- ▶ *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and **Republication of the Declaration***, 85 FR 79190-01 (Dec. 3, 2020, published 9, 2020);
- ▶ *Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 7872-02 (Jan. 28, 2021, published Feb. 2, 2021);
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- ▶ *Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 14462-02 (Mar. 11, 2021, published Mar. 16, 2021).

Case Law on Product Liability PREP Act Litigation



- ▶ *Kehler v. Hood*, No. 4:11CV1416 FRB, 2012 WL 1945952 (E.D. Mo. May 30, 2012) (H1N1 Vaccination).

Case Law on (non-Nursing Home) Med Mal PREP Act Litigation



- ▶ *Casabianca v. Mount Sinai Med. Ctr., Inc.*, 2014 NY Slip Op 33583(U), 2014 WL 10413521 (N.Y. Sup. Ct., N.Y. Cty. Dec. 2, 2014) (H1N1 Vaccination);
- ▶ *Parker v. St. Lawrence Cty. Pub. Health Dep't*, 102 A.D.3d 140, 954 N.Y.S.2d 259 (App. Div. 3rd Dept. 2012) (H1N1 Vaccination); and
- ▶ *Kehler v. Hood*, No. 4:11CV1416 FRB, 2012 WL 1945952 (E.D. Mo. May 30, 2012) (H1N1 Vaccination).

Case Law on Nursing Home PREP Act COVID Litigation



- ▶ *McCalebb v. AG Lynwood, LLC*, No. 2:20-CV-09746-SB-PVC, 2021 WL 911951 (C.D. Cal. Mar. 1, 2021).
- ▶ *Robertson v. Big Blue Healthcare, Inc.*, No. 220CV02561HLTTJJ, 2021 WL 764566 (D. Kan. Feb. 26, 2021);
- ▶ *Saunders v. Big Blue Healthcare, Inc.*, No. 220CV02608HLTTJJ, 2021 WL 764567 (D. Kan. Feb. 26, 2021);
- ▶ ***Garcia v. Welltower*, No. SACV2002250 JVSKESEX, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021);**
- ▶ *Lyons v. Cucumber Holdings, LLC*, No. CV2010571JFWJPRX, 2021 WL 364640 (C.D. Cal. Feb. 3, 2021);
- ▶ *Dupervil v. All. Health Operations, LCC*, No. 20CV4042PKCPK, 2021 WL 355137 (E.D.N.Y. Feb. 2, 2021);
- ▶ *Grohmann v. HCP Prairie Vill. KS OPCO LLC*, No. 20-2304-DDC-JPO, 2021 WL 308550 (D. Kan. Jan. 29, 2021);
- ▶ *Goldblatt v. HCP Prairie Vill. KS Opco LLC*, No. 20-2489-DDC-KGG, 2021 WL 308158 (D. Kan. Jan. 29, 2021);
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- ▶ *Fortune v. Big Blue Healthcare, Inc.*, No. 2:20 -CV-2318-HLT-JPO, 2020 WL 4815097 (D. Kan. Aug. 19, 2020);
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- ▶ *Lutz v. Big Blue Healthcare, Inc.*, 480 F. Supp.3d 1207 (D. Kan. Aug. 19, 2020);
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- ▶ *Eaton v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2291- HLT-JPO, 2020 WL 4815085 (D. Kan. Aug. 19, 2020);
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- ▶ *Baskin v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2267-HLT-JPO, 2020 WL 4815074 (D. Kan. Aug. 19, 2020);
- ▶ *Harris v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2266-HLT-JPO, 2020 WL 4815098 (D. Kan. Aug. 19, 2020);
- ▶ *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp.3d 518 (D.N.J. Aug. 12, 2020).

Case Law on Wage Claim PREP Act COVID Litigation



- ▶ *Haro v. Kaiser Found. Hosps.*, No. CV 20-6006-GW-JCX, 2020 WL 5291014 (C.D. Cal. Sept. 3, 2020).

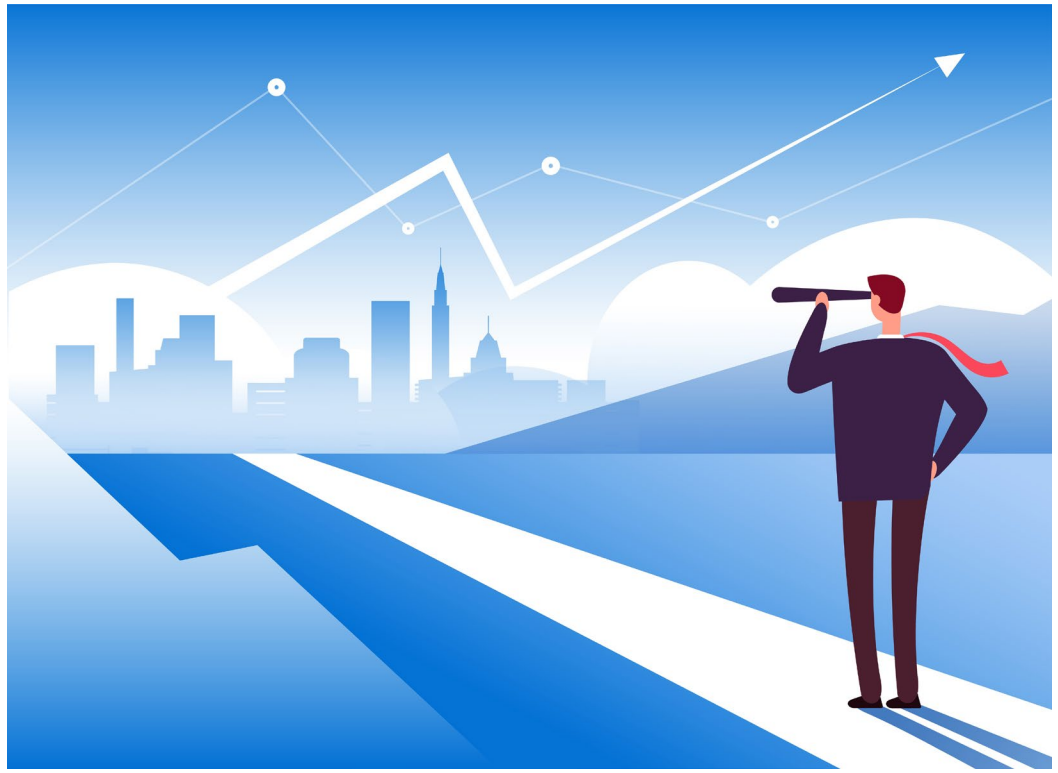
What to do

➤ Risk Assessment / Underwriting

➤ Manufacturers and Distributors

➤ Providers

Gazing Into the Future ...





QUESTIONS?

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