INDIANA 2021 HEALTHCARE UPDATE AND OVERVIEW

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INTRODUCTION AND OVERVIEW

This Article provides an overview of notable healthcare law updates in Indiana that have been a focus for legal practitioners this past year. First, this Article will discuss Indiana Medical Malpractice Act updates, State COVID-19 Immunity Laws, provide a COVID-19 Vaccination update, and a healthcare privacy update. Lastly, this Article will highlight a notable Seventh Circuit Opinion creating a private right of action for violation of residents' rights.

I. MEDICAL MALPRACTICE ACT UPDATE

Cutchin v. Beard is a matter that came before the Indiana Supreme Court from the U.S. Court of Appeals for the Seventh Circuit, which certified two questions. The first was whether Indiana's Medical Malpractice Act prohibits the Patient Compensation Fund from contesting the Act's applicability to a claim after the claimant concludes a court-approved settlement with a covered healthcare provider. The second was whether Indiana's Medical Malpractice Act applies to claims brought against qualified providers for individuals who did not receive medical care from the provider, but who are injured as a result of the provider's negligence in providing medical treatment to someone else.[1]

In *Cutchin*, a grandmother and her adult granddaughter were involved in an automobile accident which caused the death of the grandmother as well as a mother and daughter in another vehicle.[2] Immediately prior to the accident, the granddaughter saw her grandmother swallow two opiates prescribed by her physician.[3] The husband and father of decedents filed a complaint with the IDOI against the grandmother's physician/clinic under the Indiana Medical Malpractice Act, as well as a civil action in the Southern District of Indiana under its diversity jurisdiction, alleging medical malpractice.[4] Plaintiff claimed the physician breached the standard of care by failing to warn her of operating a vehicle while under the influence of prescribed medications, screen her for cognitive impairment caused by the medications, adjust medications to address issues with muscle control, and ask the BMV to assess her driving ability.[5]

Plaintiff later amended the Complaint to seek a declaratory judgment that the Indiana Medical Malpractice Act applied in that plaintiff should be considered a

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1. Cutchin v. Beard, 171 N.E.3d 991 (Ind. 2021).
2. *Id.* at 993.
3. *Id.*
4. *Id.* at 993-94.
5. *Id.* at 994.

"patient" within the meaning of the Act.[6]

The Court held that the Act's definition of "patient" falls into two categories:

- A traditional patient (i.e., physician-patient relationship); or
- A 3rd party with a claim against a health-care provider under state law.[7]

Indiana Code section 34-18-2-22 says that a third party who did not receive medical care from a provider but who has a claim due to a provider's malpractice is also a "patient" under the Act.[8] "The Act defines both what kind of claim and what kind of claimant are subject to the Act."[9]

Ultimately, the Court rejected the argument from the Patient Compensation Fund that the injured third party has only a generic negligence claim not subject to the Act.[10]

Notably, Justice Stephen David wrote a concurring opinion expressing concern about the majority's interpretation of the statute.[11] His opinion also expressed concern that plaintiffs not asserting derivative claims as part of a traditional patient's claim might be better served by filing in court and not being forced to have a Medical Review Panel review it first.[12]

II. COVID-19 VACCINE UPDATE

The coronavirus pandemic has burdened the world with severe illness, local government shutdowns, community lockdowns, mask mandates, death, and more. With such severe effects on the global population and normal daily life, the development, approval, and rollout of COVID-19 vaccines could not have come soon enough. However, with the rollout of the vaccines came much uncertainty and misinformation. This Article aims to provide background information on the vaccine rollout and the difference between emergency use authorization and full approval of the vaccines. This Article will also discuss various considerations that employers face in determining whether to require vaccination for their employees and legal requirements, namely religious and disability-related exemptions, that must be provided.

A. Background on COVID-19

COVID-19, or coronavirus, is a respiratory virus caused by SARS-CoV-2 and can cause some individuals to become very ill.[13] According to the World Health Organization ("WHO"), on December 31, 2019, the virus, originally thought to be pneumonia, was first identified in Wuhan, China and later confirmed to be a

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6. *Id.*
7. *Id.* at 995.
8. IND. CODE § 34-18-2-22 (2021).
9. *Cutchin*, 171 N.E.3d at 995.
10. *Id.* at 997.
11. *Id.* at 998 (David, J., concurring).
12. *Id.*
13. *See Frequently Asked Questions*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/faq.html [https://perma.cc/Q8M9-UQFD].

novel coronavirus on January 9, 2020.[14] On March 6, 2020, the Indiana Department of Health confirmed the first case of COVID-19 in the state.[15] That same day, the Indiana Governor issued Executive Order 20-02 which declared a public health emergency throughout the state of Indiana because of the COVID-19 outbreak.[16] As of September 2, 2021, that Executive Order had been extended eighteen times as the virus remains present in every county throughout the state, totaling 855,000 confirmed cases and roughly 14,000 deaths.[17]

B. Timeline of Vaccine Rollout

In February 2020, WHO convened a forum on the coronavirus, covering the topic of research and development of vaccines.[18] In April 2020, WHO committed to accelerating the development of a COVID-19 vaccine.[19] In October 2020, WHO made a call to manufacturers to apply for approval for Emergency Use Authorization of a vaccine.[20] On December 11, 2020, the U.S. Food and Drug Administration ("FDA") issued its Decision Memorandum recommending issuance of an Emergency Use Authorization ("EUA") for the Pfizer vaccine in individuals 16 years of age and older.[21] On December 18, 2020, the FDA issued its Decision Memorandum recommending issuance of an EUA for the Moderna vaccine in individuals 18 years of age and older.[22] The first doses of COVID-19 vaccines were available in Indiana on December 14, 2020.[23] Most recently, on August 23, 2021, the FDA granted full approval to the Pfizer vaccine.[24]

C. Emergency Use Authorization Versus Full FDA Approval

EUA is a mechanism to streamline a vaccine's availability during public health emergencies.[25] Vaccines are still rigorously tested, but EUA allows the

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14. *See Listings of WHO's response to COVID-19*, WORLD HEALTH ORG., https://www.who.int/news/item/29-06-2020-covidtimeline (Jan. 29, 2021) [https://perma.cc/D37U-3SXW].

15. *See 2019 Novel Coronavirus (COVID-19)*, IN.GOV, https://www.coronavirus.in.gov/ [https://perma.cc/2ABE-VE9Z].

16. Ind. Exec. Order No. 20-02 (March 6, 2020).

17. Ind. Exec. Order No. 21-22 (August 30, 2021).

18. *Listings of WHO's response to COVID-19, supra* note 14.

19. *Id*.

20. *Id*.

21. FDA, EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM 55 (2020), https://www.fda.gov/media/144416/download [https://perma.cc/T5CE-MMC5].

22. FDA, EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM 60 (2020), https://www.fda.gov/media/144673/download [https://perma.cc/3NRZ-F4ZQ].

23. *See 2019 Novel Coronavirus (COVID-19)*, *supra* note 15.

24. *See generally BLA Approval*, U.S. FOOD & DRUG ADMIN. (Aug. 23, 2021). https://www.fda.gov/media/151710/download [https://perma.cc/9HYP-6TG2].

25. *Emergency Use Authorization for Vaccines Explained,* U.S. FOOD & DRUG ADMIN.,

FDA to permit the use of a non-fully approved medical product in an emergency. Clinical trials utilizing "tens of thousands" of participants are still conducted and must comply with FDA standards.[26] EUA is authorized by statute. 21 U.S.C. § 360bbb-3 provides that the Secretary of the FDA "may authorize the introduction into interstate commerce, during the effective period of a [public health emergency], of a drug, device, or biological product intended for use in an actual or potential emergency" EUA is permitted for a product when the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention, determines that "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials . . . it is reasonable to believe that" 1) the vaccine may be effective in preventing the virus, 2) the benefits of the vaccine outweigh the risks of the vaccine, and 3) there is no adequate and approved alternative product to prevent or treat the virus.[27] The EUA statute places numerous conditions on unapproved products as well.

If a vaccine, or product, receives full FDA approval, that means that it has undergone the FDA's standard process for medical products. John Hopkins Medicine put it succinctly: "Full approval is granted when, over time, the FDA has amassed even more scientific evidence to support use of the COVID-19 vaccines, showing that the benefits of the vaccine are greater than its risks, and that the vaccines can be manufactured reliably, safely and with consistent quality."[28] The FDA review process consists of the following steps: 1) clinical trials, 2) assessment of risks and benefits, 3) continuous monitoring after approval, and 4) strict adherence to manufacturing guidelines.[29]

D. EEOC Requirements and Guidance

Organizations, whether health care organizations, businesses, law firms, or otherwise, navigating vaccination policies should look to the Equal Employment Opportunity Commission ("EEOC") for guidance in implementing vaccine requirements. The EEOC advises that employers should consider simply recommending employees get the vaccine rather than requiring vaccination.[30] Pursuant to the ADA, an employee may be entitled to an exemption from

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https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (Nov. 20, 2020) [https://perma.cc/H9HK-WWJ7].

26. *Id*.

27. 21 U.S.C. § 360bbb-3(c).

28. *Full FDA Approval of a COVID-19 Vaccine: What You Should Know*, JOHNS HOPKINS MEDICINE (Aug. 23, 2021), https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/full-fda-approval-of-a-covid-19-vaccine-what-you-should-know.

29. *Id*.

30. Notably, with the President's September 9, 2021, announcement, employers with 100 or more employees will soon be required to mandate the vaccination for its staff pursuant to Department of Labor rule.

mandatory vaccination requirements.[31] In addition, the Civil Rights Act requires that religious exemptions be provided.[32] However, the EEOC does not prevent any employer from requiring employees to be vaccinated against the coronavirus so long as reasonable accommodations under the law are available.[33]

42 U.S.C. § 12111(10)(A) provides that once an employer is on notice that an employee's religious belief or disability prevents them from getting the vaccine, the employer must provide a reasonable accommodation unless it would impose an undue hardship. Undue hardship is defined as "an action requiring significant difficulty or expense, when considered in light of the factors set forth in subparagraph (B)."[34] In determining whether something is an undue hardship, the following factors should be considered:

> (i) the nature and cost of the accommodation needed under this chapter;
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> (ii) the overall financial resources of the facility or facilities involved in the provision of the reasonable accommodation; the number of persons employed at such facility; the effect on expenses and resources, or the impact otherwise of such accommodation upon the operation of the facility;
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> (iii) the overall financial resources of the covered entity; the overall size of the business of a covered entity with respect to the number of its employees; the number, type, and location of its facilities; and
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> (iv) the type of operation or operations of the covered entity, including the composition, structure, and functions of the workforce of such entity; the geographic separateness, administrative, or fiscal relationship of the facility or facilities in question to the covered entity.[35]

The EEOC suggests that a reasonable accommodation could include wearing a face mask, social distancing, modifying shifts, periodic testing, or working remotely.[36] The EEOC also reminds employers that an employee's vaccination information must be kept confidential under the ADA.[37] While there is nothing that prevents an employer from requiring proof, or documentation, of vaccination,

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31. *Pandemic Preparedness in the Workplace and the Americans with Disabilities Act*, U.S. EQUAL EMP. OPPORTUNITY COMM'N (Oct. 9, 2009), https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act [https://perma.cc/7PZM-NMLF].

32. *Id*.

33. *Pandemic Preparedness in the Workplace and the Americans with Disabilities Act*, *supra* note 31.

34. 42 U.S.C. § 12111(10)(A).

35. *Id*.

36. *Pandemic Preparedness in the Workplace and the Americans with Disabilities Act*, *supra* note 31.

37. *Id*.

that information is considered medical information and must be kept confidential.[38]

Further, the ADA's restrictions on disability-related inquiries still applies even if an employer requires vaccination.[39] In other words, just because an employer mandates employees get vaccinated against the coronavirus and can require proof of vaccination, employers still must abide by the ADA's restrictions on medical examinations and questions that would elicit information about someone's disability. The ADA provides, in part "[a] covered entity shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be job-related and consistent with business necessity."[40]

> A medical examination is job-related and consistent with business necessity, as required by the ADA, when an employer has a reasonable belief based on objective evidence that a medical condition will impair an employee's ability to perform essential job functions or that the employee will pose a threat due to a medical condition; the employer's reasonable belief must be based on objective evidence obtained, or reasonably available to the employer, prior to making a disability-related inquiry or requiring a medical examination, and such a belief requires an assessment of the employee and his/her position and cannot be based on general assumptions.[41]

The EEOC has stated that "[t]he act of administering the vaccine is not a "medical examination" under the ADA because it does not seek information about the employee's physical or mental health.[42] "However, because the pre-vaccination screening questions are likely to elicit information about a disability, the ADA requires that they must be "job related and consistent with business necessity" when an employer or its agent administers the COVID-19 vaccine."[43] Further, it is not a disability-related inquiry for an employer to ask about or request proof of documentation that an employee is vaccinated.[44] EEOC guidance is evolving in light of updates and the progression of COVID-19 variants.

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38. *Id*.

39. *Id*.

40. 42 U.S.C. § 12112(d)(4)(A).

41. *See* Wright v. Illinois Dept. of Children and Family Services, 798 F. 3d 513, 522-523 (7th Cir. 2015) (citing Americans with Disabilities Act of 1990, § 102(d)(4)(A), 42 U.S.C.A. § 12112(d)(4)(A)).

42. *Pandemic Preparedness in the Workplace and the Americans with Disabilities Act*, *supra* note 31.

43. *Id*.

44. *Id*.

E. Exemptions

It is imperative that employers abide by the ADA and Civil Rights Act in providing reasonable accommodations for those requesting a religious or ADA exemption from any vaccination policy.

Once a facility is on notice that an employee's religious belief prevents them from getting the vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship.[45] In addition, a vaccine mandate may cause an issue for employees with a disability. If an employee with a disability cannot get the vaccine, the employer would have to show that an unvaccinated employee would pose a direct threat due to a "significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation."[46] In either scenario, the facility cannot exclude the employee from the workplace unless there is no way to provide a reasonable accommodation. Employers would need to determine whether accommodations can be made for the employee, such as working remotely, not providing direct patient care in a health care setting, wearing a mask, submitting to regular testing, or taking Family and Medical Leave.

F. Religious Exemption

With any vaccine mandate, employers must provide religious exemptions under Title VII of the Civil Rights Act. With more organizations moving forward with COVID-19 vaccine mandates, it is expected that a wave of religious exemption requests will follow. Once a facility is on notice that an employee's religious belief prevents them from getting the vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship, as defined above.[47]

"Religion" is very broadly defined and encompasses not only organized religions, but also informal beliefs.[48] However, the religious belief must be "sincerely held". Courts have found that veganism can be considered a sincerely held religious belief. As such, an employee need not provide proof that they are a member of a recognized religious group but may be subjected to further inquiry as to whether their beliefs are sincerely held. Because religion is so broad, the EEOC advises that an employer should ordinarily assume that an employee's request is based on a sincerely held religious belief.

However, if an employer becomes aware of facts that provide an objective basis for questioning either the religious nature or the sincerity of a particular belief, the employer can request additional supporting information.[49] In that case, the employer may ask the employee to provide an explanation of his or her sincerely held religious beliefs and, if necessary, appropriate documentation

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45. 42 U.S.C. § 12111(10)(A).
46. 29 C.F.R. § 1630.2(r) (2021).
47. 42 U.S.C. § 12111(10)(A).
48. *See* 29 C.F.R. § 1605.1 (2021).
49. *See id*. pt. 1605.

regarding the religious belief. Documentation that an employer can request could include written religious materials describing the religious belief or practice, written statements, or other documents from third parties, such as religious leaders, practitioners, or others with whom the employee has discussed his or her beliefs, or who have observed the employee's past adherence to the claimed religious practice.

G. Disability-Related Exemption

Similarly, as mentioned above, an employer mandating COVID-19 vaccination for its employees must abide by the ADA's prohibition of discrimination based on a person's disability. The ADA requires an employer to provide reasonable accommodations for employees who do not get the COVID-19 vaccine due to a disability. Under the ADA, disability is defined as:

> (i) A physical or mental impairment that substantially limits one or more of the major life activities of such individual;
> (ii) A record of such an impairment; or
> (iii) Being regarded as having such an impairment as described in paragraph (l) of this section. This means that the individual has been subjected to an action prohibited by the ADA as amended because of an actual or perceived impairment that is not both "transitory and minor."[50]

As a best practice, the EEOC recommends that an employer introducing a mandatory COVID-19 vaccination policy notify all employees that the employer will consider requests for reasonable accommodation on a case-by-case basis. The EEOC also recommends that before introducing a mandatory vaccination policy, employers should provide leadership with clear information about how to handle accommodation requests from employees.

The ADA only requires that employers offer a reasonable accommodation if it does not pose an undue hardship, meaning a significant difficulty or expense. The EEOC recommends that employers consider all options before denying a request for accommodation. "The proportion of employees in the workplace who already are partially or fully vaccinated against COVID-19 and the extent of employee contact with non-employees, who may be ineligible for a vaccination or whose vaccination status may be unknown, can impact the ADA undue hardship consideration. Employers may rely on recommendations from the CDC when deciding whether an effective accommodation is available that would not pose an undue hardship."[51] Examples of a reasonable accommodation per the EEOC include wearing a face mask, working at a social distance from coworkers or non-employees, teleworking, or being reassigned.

The EEOC also provides a list of medical conditions that easily qualify as a

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50. 29 C.F.R. § 1630.2(g) (2021).

51. *Pandemic Preparedness in the Workplace and the Americans with Disabilities Act*, *supra* note 31.

disability. This includes:

> "[d]eafness . . . ; blindness . . . ; an intellectual disability (formerly termed mental retardation) . . . ; partially or completely missing limbs or mobility impairments requiring the use of a wheelchair . . . ; autism . . . ; cancer . . . ; cerebral palsy . . . ; diabetes . . . ; epilepsy . . . ; Human Immunodeficiency Virus (HIV) infection . . . ; multiple sclerosis . . . ; muscular dystrophy . . . ; and major depressive disorder, bipolar disorder, post-traumatic stress disorder, obsessive compulsive disorder, and schizophrenia."[52]

III. STATE CIVIL IMMUNITY RELATED TO COVID-19

During the 2021 Legislative Session, the Indiana Legislature passed House Enrolled Act 1002 (eff. March 1, 2020). This law protects health care providers from professional discipline for certain acts or omissions arising from a disaster emergency unless the act or omission constitutes gross negligence, willful or wanton misconduct, or intentional misrepresentation. It also provides immunity from civil liability to certain persons, entities, and facilities providing health care and other services for certain acts or omissions related to the provision of health care services and other services during a state disaster emergency.

Indiana Code section 34-30-13.5-1(b) states that "[a] person providing health care services or emergency medical services, whether in person or through telemedicine services permitted by IC 25-1-9.5, at a facility or other location where health care services or emergency medical services are provided may not be held civilly liable for an act or omission relating to the provision or delay of health care services or emergency medical services arising from a state disaster emergency declared under IC 10-14-3-12 to respond to COVID-19."[53] "An employer, including an agency that provides or arranges health care services or emergency medical services, of a person described in subdivision (1) may not be held civilly liable for an act or omission relating to the provision or delay of health care services or emergency medical services arising from a state disaster emergency declared under IC10-14-3-12 to respond to COVID-19."[54]

Indiana Code section 34-30-32-2 defines "[a]rising from COVID-19," for purposes of section 10.5 of this chapter, section 34-12-5, and section 34-13-3-3, as "an injury or harm caused by or resulting from:

- (1) the actual, alleged, or possible exposure to or contraction of COVID-19; or
- (2) services, treatment, or other actions performed for COVID-19."[55]

Indiana Code section 34-13-3-3(b) provides that "[a] governmental entity or an employee acting within the scope of the employee's employment is not liable

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52. 29 C.F.R. § 1630(j)(3)(iii) (2021).
53. IND. CODE § 34-30-13.5-1(b)(1) (2021).
54. *Id.* § 34-30-13.5-1(b)(2).
55. *Id.* § 34-30-32-2.

for an act or omission arising from COVID-19 unless the act or omission constitutes gross negligence, willful or wanton misconduct, or intentional misrepresentation. If a claim described in this subsection is:

> (1) a claim for injury or death resulting from medical malpractice; and
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> (2) not barred by the immunity provided under this subsection; the claimant is required to comply with all of the provisions of IC 34-18 (Indiana Medical Malpractice Act)."[56]

The law also provides what is *not* gross negligence, willful or wanton misconduct, fraud or intentional misrepresentation. This includes providing services without required personal protective equipment caused by a shortage or an inability to timely acquire personal protective equipment in response to or arising from a state disaster emergency declared under IC 10-14-3-12 to respond to COVID-19.[57] Additional examples include the following:

- Providing services without access to adequate or reliable testing for COVID-19, even if the COVID-19 testing that was used received emergency use authorization from the federal Food and Drug Administration.
- Using equipment, medicine, or supplies to treat or help prevent the transmission of COVID-19 in a manner that is not approved by the federal Food and Drug Administration.
- Providing services that are outside of an individual's expertise or specialty but within the individual's scope of practice under IC 16 or IC 25.[58]

IV. VACCINE MANDATE LITIGATION

As mentioned above, religion is defined broadly under the Civil Rights Act. Notably, in *Chenzira v. Cincinnati Children's Hospital Medical Center*, a lawsuit filed in the U.S. District Court for the Southern District of Ohio, the defendant hospital was sued by its long-time employee for religious discrimination when it terminated her due to her refusal to get the flu vaccine.[59] She alleged that because she was vegan and did not ingest animal by-products, it was her "moral and ethical belief which was sincerely held with the strength of traditional religious views" that prevented her from being vaccinated.[60] The hospital attacked her argument contending that veganism did not qualify as a religion.[61] In the court's order denying the hospital's motion to dismiss, the court found that it was

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56. *Id.* § 34-13-3-3(b).
57. *See id.* § 34-30-13.5-1(c)
58. *Id.* §§ 34-30-13.5-1(c)(2)-(4).
59. No. 1:11-cv-00917, 2012 WL 6721098 (S.D. Ohio, Dec. 27, 2012).
60. *Id.* at *4.
61. *Id.*

plausible that the employee "could subscribe to veganism with a sincerity equating that of traditional religious views."[62] The case was later settled.

Moreover, courts are upholding corporate vaccination mandates finding that they violate no federal law. In June 2021, the U.S. District Court for the Southern District of Texas dismissed a lawsuit brought by 117 employees of Houston Methodist Hospital attempting to block its COVID-19 vaccine requirement.[63] The plaintiffs in that case alleged that the vaccines were "experimental and dangerous" and that if fired for refusing, they would be wrongfully terminated.[64] The court found that "Texas law only protects employees from being terminated for refusing to commit an act carrying criminal penalties to the worker."[65] Further, the court found that "[r]eceiving a COVID-19 vaccination is not an illegal act, and it carries no criminal penalties" in stating that the complaint failed to specify what illegal acts the plaintiffs were alleged to have been asked to perform.[66] The plaintiffs have appealed to the Fifth Circuit Court of Appeals.

Closer to home, the U.S. District Court for the Northern District of Indiana upheld Indiana University's vaccination policy in July 2021. In *Klaassen v. Trustees of Indiana University,* eight IU students filed suit against the university arguing that the policy violated the Fourteenth Amendment.[67] In a 101-page opinion denying the students motion for preliminary injunction, the court found that IU can "pursue a reasonable and due process of vaccination in the legitimate interest of public health for its students, faculty, and staff."[68] The plaintiffs appealed the court's order on the preliminary injunction to the Seventh Circuit Court of Appeals.[69] The Court of Appeals held that university's policy did not violate Due Process Clause and denied the Plaintiff's Motion.[70]

Shortly after the Pfizer vaccine received full FDA approval, President Biden came out with what the White House termed the Pathway Out of the Pandemic. This plan contained many aspects aimed at getting more people vaccinated and two aspects of his plan have received a lot of media attention and prompted litigation. First, is the requirement related to employers with 100+ employees and the second is the requirement related to healthcare workers.

OSHA developed an emergency rule that requires all employers with 100 or more employees to get vaccinated or any workers who opt out of vaccination would have to produce a negative test result on at least a weekly basis before

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62. *Id*.

63. Bridges v. Houston Methodist Hosp., 543 F. Supp. 3d 525 (S.D. Tex. 2021), *aff'd sub nom.* Bridges v. Methodist Hosp., No. 21-20311, 2022 WL 2116213 (5th Cir. June 13, 2022).

64. *Id*. at 526.

65. *Id*. (citing Sabine Pilot Serv., Inc. v. Hauck, 687 S.W.2d 733, 735 (Tex. 1985)).

66. *Id*.

67. Klaassen v. Tr. of Ind. Univ., 549 F. Supp. 3d 836, 846 (N.D. Ind. 2021), *vacated and remanded*, 24 F.4th 638 (7th Cir. 2022).

68. *Id*. at 843.

69. Notice of Appeal, Klaassen v. Tr. of Ind. Univ., 549 F. Supp. 3d 836, 846 (N.D. Ind. 2021) No. 1:21-CV-00238.

70. Klassen v. Tr. of Ind. Univ., 24 F.4th 638, 640 (7th Cir. 2022).

coming to work. The emergency rule on Vaccination and Testing was published in the Federal Register on November 5, 2021.[71] This also acts as a proposal for a permanent standard and OSHA has decided to extend the comment period for that rule by 45 days.[72]

This was certainly not going to come without legal challenges. In fact, Indiana's Attorney General Todd Rokita signed on to a letter to the President in September asking him to reconsider the requirement. The U.S. circuit court for the Sixth Circuit issued a nationwide stay on the rule the next day. However, as of Dec. 17, 2021, the stay has been lifted and the rule is currently in effect. The Supreme Court has agreed to take up the legal challenges to the OSHA rule and will hear oral arguments on Jan. 7, 2022. The ETS remains in effect until then, after which its fate will be decided by the high court.

President Joe Biden's announcement on September 9, 2021 also included that the CDC "is taking action to require COVID-19 vaccinations for workers in most health care settings that receive Medicare or Medicaid reimbursement."[73] This includes hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies.[74] President Biden previously announced that long term care facilities would be required to mandate vaccinations for its staff on August 18, 2021. The White House announced that "[t]his action will create a consistent standard across the country, while giving patients assurance of the vaccination status of those delivering care."[75]

Similar to the OSHA rule, CMS' emergency rule also prompted litigation. The healthcare mandate, issued on November 4, requires all workers at Medicare- and Medicaid-funded healthcare facilities, including more than 15,000 nursing homes, to get vaccinated against COVID-19. It also threatens penalties for non-compliant healthcare provider organizations.[76]

On November 29, 2021, the United States District Court for the Eastern District of Missouri issued a preliminary injunction against the implementation and enforcement in ten states of Medicare and Medicaid Programs in *State of Missouri, et al. v. Joseph R. Biden, Jr.*[77] On November 30, 2021, in *State of Louisiana v. Becerra*, the U.S. District Court for the Western District of Louisiana granted a nationwide preliminary injunction, immediately halting the

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71. 29 CFR §§ 1910.501-509 (2021).

72. *COVID-19 Vaccination and Testing ETS*, U.S. DEP'T LAB. https://www.osha.gov/coronavirus/ets2 [https://perma.cc/UA77-XPML].

73. *National COVID-19 Preparedness Plan*, WHITE HOUSE, https://www.whitehouse.gov/covidplan/ [https://perma.cc/T47C-EDCN].

74. *Id*.

75. *Id*.

76. *See External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule*, CMS.GOV (Jan. 20, 2022), https://www.cms.gov/files/document/cms-omnibus-covid-19-health-care-staff-vaccination-requirements-2021.pdf [https://perma.cc/G3W2-6V4D].

77. Memorandum and Order, Missouri v. Biden, No. 4:21-cv-01329-MTS (E.D. Mo. Nov. 29, 2021), *available at* https://ago.mo.gov/docs/default-source/press-releases/cms-injunction.pdf?sfvrsn=ed822d9d_2 [https://perma.cc/VY3P-QCXJ]

Centers for Medicare and Medicaid Services' (CMS) federal mandate requiring employees, volunteers, and third-party contractors working at healthcare facilities to be vaccinated against COVID-19.[78] CMS has appealed both of these decisions and has filed motions for stays of these orders. In the meantime, CMS has suspended activities related to the implementation and enforcement of this rule pending future developments in the litigation.

V. HEALTHCARE PRIVACY UPDATE

Indiana Code 16-39-11-5, pertaining to Health Records, was amended this year in relation to COVID-19 immunization records. House Enrolled Act 1405 was passed by the Indiana Legislature and provides that immunization passports may *not* be issued or required in the state. However, the law does not prohibit the state or a local unit from doing any of the following:

- Maintaining, creating, or storing a medical record of an individual's immunization status.
- Providing a medical record of an individual's immunization status to the individual's medical provider in accordance with the federal Health Insurance Portability and Accountability Act (HIPAA) (P.L.104-191).
- Providing the individual with a record of an immunization at the time the individual receives the immunization or upon request by the individual.

  Maintaining an immunization record for the purpose of public health administration.[79]

A. HIPAA & COVID-19

As an introduction, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

The Office for Civil Rights at Health and Human Services ("HHS") issued guidance on December 18, 2020[80] on how HIPAA permits covered entities and

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78. Memorandum Ruling, Louisiana v. Becerra, No. 3:21-CV-03970 (W.D. La. Nov. 30, 2021), *available at* https://www.alabamaag.gov/Documents/news/CMS%20Nationwide%20Injunction.pdf [https://perma.cc/Y34L-GNWE].

79. IND. CODE § 16-39-11-5(1)-(4) (2021).

80. U.S. DEP'T HEALTH & HUM. SERVS. OFF. OF C.R., HIPAA, HEALTH INFORMATION EXCHANGES, AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR PUBLIC HEALTH PURPOSES (2020), *available at* https://www.hhs.gov/sites/default/files/hie-faqs.pdf [https://perma.cc/C8EE-8VX3].

their business associates to use Health Information Exchanges ("HIEs") to disclose protected health information ("PHI") for public health activities of a public health authority ("PHA"). A covered entity is required to provide individuals with notice that it discloses PHI for public health purposes in the Notice of Privacy Practices.

For example, during the COVID-19 public health emergency, an HIE can transmit patient test results it receives in the HIE's role as a covered health care provider's business associate, in response to a PHA's request, regardless of whether the HIE's business associate agreement ("BAA") with the provider permits such disclosure.

Further, a state PHA can engage an HIE to collect test results and associated patient information from health care providers and then transmit that information into the state's electronic contact tracing systems.

VI. PRIVATE RIGHT OF ACTION – RESIDENTS' RIGHTS

In *Talevski v. Health & Hospital Corp., et al*., Plaintiff Gorgi Talevski, filed a complaint in the Northern District of Indiana against The Health and Hospital Corporation of Marion County ("HHC"), American Senior Communities, LLC ("ASC"), and Valparaiso Care and Rehabilitation ("VCR") for violations of 42 U.S. § 1983, specifically alleging violations of the Federal Nursing Home Reform Act ("FNHRA").[81]

The FNHRA established and codified certain rights to which all residents of long-term care facilities are entitled. In Indiana violation of resident rights can result in statutory fines and penalties for violators but there was not private cause of action associated with such violations.

The complaint alleged that VCR violated the rights of former resident, Mr. Talevski, by using chemical restraints and refusing to accept him back after a stay at a NeuroPsych unit. If true, the facts would support a determination that his rights under FNHRA were violated. The District Court granted defendants' motion to dismiss finding that FNHRA does not create a private right of action under section 1983 and plaintiff appealed.

The Seventh Circuit determined Talevski had met the three elements for an implied private right of action: 1) Congress intended the FNHRA to benefit nursing home residents; 2) the FNHRA's requirements are "not so vague and amorphous that its enforcement would strain judicial competence"; and 3) the provision giving rise to the asserted right is couched in mandatory rather than precatory terms.[82] The Court stated that "a common-sense reading of [the FNHRA's] provisions leaves no room for disagreement" that facilities "must protect and promote the right against chemical restraints, must allow residents to remain in the facility, must not transfer, and must not discharge the resident; these are unambiguous obligations".[83] The Court, in rejecting VCR's argument that the

81. Talevski v. Health & Hosp. Corp., 6 F.4th 713 (7th Cir. 2021).

82. *Id*. at 719-20.

83. *Id*. at 720.

FNHRA forecloses section 1983 claims because there are other mechanisms for recourse, found that section 1396r(h)(8) expressly states that "[t]he remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law."[84] As such, the Seventh Circuit held that it was error for the district court to dismiss the case.

While this decision may still be appealed to the Supreme Court, it certainly poses a risk for nursing homes that Plaintiffs suing these facilities can now bring claims under section 1983, which they could not do before. However, in advocating for dismissal, the defendants did not raise the argument that Plaintiff's claim sounded in medical malpractice and as such, the district court lacked jurisdiction over Plaintiff's complaint. Therefore, it is unclear how a medical review panel opinion before the Indiana Department of Insurance would inform such a claim.[85]

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84. *Id*. at 721.

85. Appellees do, however, include a footnote in their brief before the Seventh Circuit that: "there is yet another remedy available to Talevski: a state-law medical malpractice claim. If VCR employees really were chemically restraining Talevski illegally, then he could bring a suit in state court advancing that claim. *See*, e.g., *Chessie Logistics Co. v. Krinos Holdings, Inc*., 867 F.3d 852, 858 (7th Cir. 2017) ("[A]s a general matter, rail carriers already have legal remedies against interference with their operations. They are the same remedies available to every property owner whose property is damaged: state law tort claims."). Talevski has not even suggested that such a remedy is inadequate. *See id*. at 858."

Brief of Appellees at 42 n.24, Talevski v. Health and Hospital Corp., 6 F.4th 713 (7th Cir. 2021) (No. 20-1664).