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## Healthcare Law

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# Healthcare Law

**Kathryn Dunnam Harden\***

## I. INTRODUCTION

This Article serves as a review of significant healthcare developments in the United States Court of Appeals for the Eleventh Circuit during this past Survey period. Specifically, this Article will cover cases, legislation, and trends involving COVID-19, healthcare fraud, and reproductive rights.

## II. COVID-19 REGULATION AND LITIGATION

The COVID-19 pandemic has now stretched over two years and has “overtaken the 1918 influenza pandemic as the deadliest disease in American history.”<sup>1</sup> The federal government, along with the individual states, have sought to issue numerous regulations and legislation to address the novel and deadly disease. COVID-19 has proved to be politically polarizing, and the various efforts to address the disease have been met with opposition. Recent regulatory efforts by the federal government are detailed below.

Effective November 5, 2021, the Occupational Safety and Health Administration (OSHA) issued an “emergency temporary standard (ETS) to protect unvaccinated employees of large employers (100 or more employees) from the risk of contracting COVID-19 by strongly encouraging vaccination.”<sup>2</sup> The rule required that “[c]overed employers must develop, implement, and enforce a mandatory COVID-19 vaccination policy, with an exception for employers that instead adopt a policy requiring employees to either get vaccinated or elect to undergo

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1. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021).

2. COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021).

regular COVID-19 testing and wear a face covering at work in lieu of vaccination.”<sup>3</sup>

In response, “[s]cores of parties—including States, businesses, trade groups, and nonprofit organizations—filed petitions for review, with at least one petition arriving in each regional Court of Appeals. The cases were consolidated in the Sixth Circuit, which was selected at random pursuant to 28 U.S.C. § 2112(a).”<sup>4</sup> In a *per curiam* opinion, the Supreme Court of the United States ultimately granted the applications seeking a stay of OSHA’s COVID-19 Vaccination and Testing ETS.<sup>5</sup> The Court held that “[a]pplicants are likely to succeed on the merits of their claim that the Secretary lacked authority to impose the mandate,” because the Occupational Safety and Health Act (The Act) does not plainly authorize the Secretary’s mandate.<sup>6</sup> In its reasoning, the Court emphasized that the Act “empowers the Secretary to set *workplace* safety standards, not broad public health measures.”<sup>7</sup> The Court contemplated that a permissible exercise of authority would be to “regulate occupation-specific risks related to COVID-19,” such as COVID-19 researchers or “risks associated with working in particularly crowded or cramped environments.”<sup>8</sup> To require large employers, however, to implement mandatory vaccine measures was too broad an exercise of power.<sup>9</sup>

Although Congress has indisputably given OSHA the power to regulate occupational dangers, it has not given that agency the power to regulate public health more broadly. Requiring the vaccination of 84 million Americans, selected simply because they work for employers with more than 100 employees, certainly falls in the latter category.<sup>10</sup>

Effective January 26, 2022, OSHA withdrew its November 2021 ETS.<sup>11</sup> Thus, employers outside of the healthcare context are not required to implement mandatory vaccine policies.

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3. *Id.*

4. Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab., Occupational Safety and Health Admin., 142 S. Ct. 661, 664 (2022).

5. *Id.* at 666–67.

6. *Id.* at 664–65.

7. *Id.* at 665 (emphasis in original).

8. *Id.* at 665–66.

9. *Id.* at 666.

10. *Id.*

11. COVID-19 Vaccination and Testing; Emergency Temporary Standard, 87 Fed. Reg. 3928 (Jan. 26, 2022).

Other regulatory efforts have fared better. Effective November 5, 2021, the Secretary of Health and Human Services and Centers for Medicare and Medicaid Services issued a rule requiring that the non-exempt staff of healthcare facilities be vaccinated against COVID-19 in order to receive funding.<sup>12</sup> The vaccine mandate was sought in order “to help protect the health and safety of residents, clients, patients, PACE participants, and staff, and reflect lessons learned to date as a result of the COVID-19 public health emergency.”<sup>13</sup> Indeed, “[a]s of mid-October 2021, over 44 million COVID-19 cases, 3 million new COVID-19 related hospitalizations, and 720,000 COVID-19 deaths have been reported in the U.S.”<sup>14</sup>

Multiple states, including two Eleventh Circuit states, Alabama and Georgia, signed onto Louisiana’s Motion for Preliminary Injunction in order to enjoin the new vaccine mandate from taking effect.<sup>15</sup> The United States District Court for the Western District of Louisiana granted the injunctive relief.<sup>16</sup> A second United States district court, the United States District Court for the Eastern District of Missouri, likewise granted an injunction against the new vaccine mandate as sought by several different states.<sup>17</sup> In both cases, the federal government then sought a stay of the injunctions in each respective United States court of appeals.<sup>18</sup> The stays were denied by both the United States Court of Appeals for the Fifth Circuit and the United States Court of Appeals for the Eighth Circuit.<sup>19</sup>

The federal government then filed applications to stay those injunctions with the Supreme Court of the United States.<sup>20</sup> In a *per curiam* opinion, the Court ultimately granted the stays on January 13, 2022.<sup>21</sup> The Court held that the “Secretary’s rule falls within the

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12. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021).

13. *Id.*

14. *Id.* at 61,556.

15. Louisiana v. Becerra, No. 3:21-CV-03970, 2021 U.S. Dist. LEXIS 229949, at \*1 (W.D. La. Nov. 30, 2021) (hereinafter *Becerra I*).

16. *Id.* at \*2–3.

17. Missouri v. Biden, No. 4:21-cv-01329, 2021 U.S. Dist. LEXIS 227410, at \*4 (E.D. Mo. Nov. 29, 2021) (hereinafter *Biden I*).

18. Louisiana v. Becerra, 20 F.4th 260, 262 (5th Cir. 2021) (hereinafter *Becerra II*); Order at 1, Missouri v. Biden, No. 21-3725 (8th Cir. 2021) (hereinafter *Biden II*).

19. *Id.*

20. Biden v. Missouri, 142 S. Ct. 647 (2022) (hereinafter *Biden III*).

21. *Id.* at 650.

authorities that Congress has conferred upon him.”<sup>22</sup> The Court reasoned:

After all, ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm. It would be the “very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19.”<sup>23</sup>

In citing to the *amici curiae* briefs filed in the subject case, the Court further noted that “healthcare workers and public-health organizations overwhelmingly support the Secretary’s rule.”<sup>24</sup> “We accordingly conclude that the Secretary did not exceed his statutory authority in requiring that, in order to remain eligible for Medicare and Medicaid dollars, the facilities covered by the interim rule must ensure that their employees be vaccinated against COVID-19.”<sup>25</sup> The Court disagreed with the States’ remaining arguments, including the argument that the vaccine mandate was arbitrary and capricious.<sup>26</sup>

Consistent with the Supreme Court, in December 2021, the United States Court of Appeals for the Eleventh Circuit upheld a district court’s denial of Florida’s request for an injunction barring enforcement of the vaccine mandate for healthcare staff.<sup>27</sup> In sum, in order to receive funding from Centers for Medicare and Medicaid Services, non-exempt healthcare staff must be vaccinated.

### III. FALSE CLAIMS ACT UPDATE

This Survey period produced another significant development in the realm of Healthcare Fraud: *Yates v. Pinellas Hematology & Oncology, P.A.*<sup>28</sup> The United States Court of Appeals for the Eleventh Circuit held that the Excessive Fines Clause of the Eighth Amendment does apply to non-intervened *qui tam* actions brought under the False Claims Act (FCA), a question previously left open by the Supreme Court of the United States.<sup>29</sup>

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22. *Id.* at 652.

23. *Id.* (quoting *Florida v. Dep’t of Health and Hum. Servs.*, 19 F.4th 1271, 1288 (11th Cir. 2021)).

24. *Id.* at 653.

25. *Id.*

26. *Id.* at 653–54.

27. *Florida v. Dep’t of Health and Hum. Servs.*, 19 F.4th at 1275.

28. 21 F.4th 1288 (11th Cir. 2021).

29. *Id.* at 1307.

*Yates* constituted a *qui tam* action filed by relator, Ms. Michele Yates.<sup>30</sup> The United States chose not to intervene in the action.<sup>31</sup> In *qui tam* actions where the United States does not intervene, the relator brings the suit “in the name of the United States.”<sup>32</sup> In these cases, the United States “generally receives between 70 and 75 percent of the recovery, with the relator receiving the rest.”<sup>33</sup> The Eleventh Circuit described these cases as “fall[ing] in a grey area between disputes amongst purely private parties and disputes pitting the United States against a private party.”<sup>34</sup>

The Excessive Fines Clause of the Eighth Amendment applies to fines imposed by the United States.<sup>35</sup> The Eleventh Circuit rejected Ms. Yates’s argument “that the monetary award here was not imposed by the United States because it was not a party to the proceedings below.”<sup>36</sup> The False Claims Act “is a federal enactment, and therefore it must comply with the Constitution.”<sup>37</sup> The monetary awards under the False Claims Act constitute fines within the context of the Eighth Amendment.<sup>38</sup> Ultimately, the Eleventh Circuit reasoned that, given the United States’ authority and power over a non-intervened *qui tam* action, the monetary award is still imposed by the United States despite it lacking formal party status.<sup>39</sup> The FCA relator is considered a government actor to trigger the Eighth Amendment, and the Excessive Fines Clause does indeed apply to non-intervened *qui tam* actions under the False Claims Act.<sup>40</sup>

The court further held that the monetary award imposed did not violate the Excessive Fines Clause.<sup>41</sup> To violate said clause, the fine must be “grossly disproportional to the gravity of a defendant’s offense.”<sup>42</sup> The Eleventh Circuit acknowledged that “a judgment of \$1.179 million based on \$755.54 in actual damages may raise an eyebrow,” but that the “optics . . . are negated when one realizes that this total is the result of Pinellas’ repeated (214) instances of fraud

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30. *Id.* at 1295.

31. *Id.* at 1296.

32. *Id.* at 1307 (quoting 31 U.S.C. § 3730(b)(1) (2010)).

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.* at 1308–09.

37. *Id.* at 1309.

38. *Id.*

39. *Id.* at 1312–13.

40. *Id.* at 1309–10.

41. *Id.* at 1316.

42. *Id.* at 1314 (quoting *U.S. v. Bajakajian*, 524 U.S. 321, 334 (1988)).

against the United States.”<sup>43</sup> Moreover, “[t]he district court here imposed the lowest-possible statutory penalty of \$5,500 for all of the 214 violations, and treble damages are mandated by the FCA.”<sup>44</sup> Thus, the award was the lowest possible sanction available under the False Claims Act and did not violate the Excessive Fines Clause.<sup>45</sup>

While the Eleventh Circuit’s holding that the Eighth Amendment’s prohibition on Excessive Fines applies to non-intervened *qui tam* actions brought under the False Claims Act is a favorable new development for defendants, it remains to be seen what monetary amount will constitute such an Excessive Fine in this context.

#### IV. REPRODUCTIVE RIGHTS

The reproductive health and rights of women continue to be matters of contention and public debate in the current political climate.

In 2019, as initially reported in *Healthcare Law*,<sup>46</sup> the Trump Administration made drastic changes to the Title X programs so that “none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning.”<sup>47</sup> The 2019 rule also eliminated the requirement for nondirective abortion counseling and referral and prohibited referral for abortion.<sup>48</sup> Notably, “Title X is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services.”<sup>49</sup> A 2019 poll conducted by the Kaiser Family Foundation showed that “[m]ost of the public (58%) oppose[d] changing the program to exclude organizations that provide abortions or referrals for abortions with other resources, while nearly four in 10 (38%) favor[ed] such changes.”<sup>50</sup>

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43. *Id.*

44. *Id.*

45. *Id.*

46. Kathryn Dunnam Harden, *Healthcare Law, Eleventh Circuit Survey*, 70 MERCER L. REV. 1053 (2019).

47. Compliance With Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019).

48. *Id.*

49. *About Title X Grants*, HHS.GOV, <https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/index.html> (last visited Mar. 9, 2022).

50. Rakesh Singh & Craig Palosky, *Poll Finds Most Americans Oppose the Trump Administration’s Changes to Restrict Title X Family Planning Funds from Clinics that also Provide or Refer for Abortion*, KAISER FAMILY FOUNDATION, <https://www.kff.org/womens-health-policy/press-release/poll-finds-most-americans-oppose-trump-administrations-changes-to-restrict-title-x-family-planning-funds-from-clinics-that-provide-or-refer-for-abortion/> (last visited Mar. 10, 2022).

In its Title X Family Planning Annual Report, the U.S. Department of Health and Human Services (HHS) Office of Population Affairs (OPA) detailed the effects of both the COVID-19 pandemic and the Trump Administration's regulatory changes on the number of clients served.<sup>51</sup> In the two-year period from 2018 to 2020, the number of clients served decreased from 3.9 million to 1.5 million.<sup>52</sup> The OPA calculated that the 2019 rule accounted for 63% of the decrease in the number of family planning clients served while the COVID-19 pandemic accounted for 37% of the decrease.<sup>53</sup> The OPA further reported that the 2019 rule "may have led to an estimated 181,477 unintended pregnancies."<sup>54</sup>

In a triumph for reproductive health advocates, the Biden Administration reinstated many provisions of the Title X programs that were eliminated by the Trump Administration.

The effect of this 2021 final rule is to revoke the requirements of the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services and eliminating requirements for strict physical and financial separation between abortion-related activities and Title X project activities, thereby reversing the negative public health consequences of the 2019 regulations.<sup>55</sup>

The 2021 rule is not without opposition. On October 25, 2021, the States of Ohio, Alabama, Arizona, Arkansas, Florida, Kansas, Kentucky, Missouri, Nebraska, Oklahoma, South Carolina, and West Virginia moved jointly for a preliminary injunction against the Quality Family Planning Rule.<sup>56</sup> These states claimed the Biden Administration's changes to Title X violate Section 1008 of the Public Health Service Act, which provides that the funds appropriated under Title X cannot be used in programs where abortion is a method of family planning.<sup>57</sup> They further contended that the Trump Administration's 2019 changes to Title X complied with section 1008

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51. OFFICE OF POPULATION AFFAIRS, TITLE X FAMILY PLANNING ANNUAL REPORT: 2020 NATIONAL SUMMARY (2021), <https://opa.hhs.gov/sites/default/files/2021-09/title-x-fpar-2020-national-summary-sep-2021.pdf>.

52. *Id.* at ES-4.

53. *Id.* at ES-5–6.

54. *Id.* at ES-5.

55. Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 Fed. Reg. 56144, 56144 (Nov. 8, 2021) (codified at 42 C.F.R. pt. 59).

56. Combined Mot. for a Prelim. Inj. and Mem. in Supp. of the Mot., *Ohio v. Becerra*, No. 1:21-cv-675, 2021 U.S. DIST. LEXIS 247120 (S.D. Ohio Dec. 29, 2021).

57. *Id.* at 2–3, 4.

because the 2019 rule (1) required Title X grantees to have financial and physical separation from abortion referral services; and (2) “forbade Title X grantees from making abortion referrals” within the Title X program.<sup>58</sup>

On December 29, 2021, the United States District Court for the Southern District of Ohio denied the States’ motion for injunctive relief.<sup>59</sup> On appeal from the district court’s denial, the United States Court of Appeals for the Sixth Circuit likewise denied the States’ motion.<sup>60</sup> The Sixth Circuit held that the States failed to show irreparable harm from the 2021 rule and, thus, failed to meet the burden for an injunction pending appeal.<sup>61</sup> The Sixth Circuit expressed no opinion on the merits of the States’ claims.<sup>62</sup> Therefore, the 2021 rule remains intact for now.

It remains to be seen whether or not the 2021 rule and its funding will effectively reverse the damage from the 2019 rule, but the Biden Administration is making steps in the right direction to prioritize the reproductive health and rights of women.

#### V. CONCLUSION

This past Survey period has seen important updates in the field of healthcare law. In the context of COVID-19, non-exempt healthcare staff must be vaccinated in order to receive federal funding. In addition, in a matter of first impression, the Eleventh Circuit held that the Excessive Fines Clause of the Eighth Amendment does apply to non-intervened *qui tam* actions brought under the False Claims Act. Finally, the Biden Administration rolled back the Trump Administration’s Title X restrictions, in a triumph for the champions of women’s reproductive health and rights.

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58. *Id.* at 7–8.

59. *Ohio v. Becerra*, No. 1:21-cv-675, 2021 U.S. Dist. LEXIS 247120, at \*15 (S.D. Ohio Dec. 29, 2021).

60. *Ohio v. Becerra*, No. 21-4235, 2022 U.S. App. LEXIS 3435, at \*21 (6th Cir. Feb. 8, 2022).

61. *Id.* at \*20–21.

62. *Id.* at \*20.