HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1013 COVID-19 Mandates and Treatment Options
SPONSOR(S): Health & Human Services Committee, Griffitts
TIED BILLS: HB 1015 **IDEN./SIM. BILLS:** SB 252

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee	12 Y, 5 N, As CS	Calamas	Calamas
2) Appropriations Committee			
3) Commerce Committee			

SUMMARY ANALYSIS

The COVID-19 pandemic caused millions of deaths around the world, including over 1.1 million in the U.S. Currently, hospitalizations and deaths from COVID-19 remain relatively low nationwide. In response, the federal government issued Emergency Use Authorizations (EUAs) and full approvals, for vaccines and treatments. The federal government also required vaccination and other preventive measures in certain settings. The pandemic led to a worldwide debate on the role of government and private employers in such public health emergencies.

Current Florida law prohibits: businesses and governments from requiring employees to be vaccinated; businesses, governments and educational institutions from requiring proof of vaccination or post-infection recovery; and schools from requiring students to wear masks or be vaccinated. Enforcement is by the Department of Legal Affairs (DLA) within the Office of the Attorney General, by the Department of Health (DOH), or by private court action, depending on the provision.

The CS/HB 1013 amends current prohibitions and creates additional prohibitions. The bill:

- Prohibits businesses, governmental entities, and educational institutions from requiring a person to take a COVID-19 test or wear a facial covering to gain access to or use their services.
- Prohibits businesses, governmental entities, and educational institutions from discriminating against a person for refusing to comply with a requirement prohibited by the bill, or current law, and specifically prohibits employment discrimination by businesses and governmental entities.
- Prohibits the use of facial coverings in health care settings, except in compliance with emergency rules required by the bill to be adopted by DOH and the Agency for Health Care Administration (AHCA)

The bill requires DLA to enforce the provisions against businesses and governmental entities, and moves enforcement of the current prohibitions against requiring documentation of vaccination or post-infection recovery from DOH to DLA. Similarly, the bill requires DOH to enforce the provisions against educational institutions, and repeals the current authority for parents and adult students to pursue declaratory and injunctive relief to enforce the current prohibitions against requiring documentation of COVID-19 vaccination or post-infection recovery.

The bill requires express informed patient consent for the use of COVID-19 treatment alternatives. Practitioners must consider treatment alternatives approved or authorized by the U.S. Food and Drug Administration, and explain the risks and benefits. It prohibits hospitals from interfering with the patient's right to choose treatment alternatives, under certain circumstances. Finally, the bill grants pharmacists licensure discipline immunity for dispensing a prescribed COVID-19 treatment alternative.

The bill has a significant, negative fiscal impact on DLA and DOH, and no impact on local government.

The bill is effective June 1, 2023.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

COVID-19

Beginning in late 2019, a coronavirus, identified as SARS-CoV-2, caused a pandemic of respiratory illness, called COVID-19, to spread worldwide. COVID-19 can be severe, and has caused millions of deaths around the world, including over 1.1 million deaths in the United States (US). It can be spread from person to person and has caused lasting health problems in some.

COVID-19 Vaccines

In 2020, the federal Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA)[1] for COVID-19 vaccines by Pfizer/BioNTech and Moderna;[2] the EUA for the J&J/Janssen vaccine was issued in 2021.[3] The FDA issued full approval for the Pfizer vaccine in August 2021,[4] and for the Moderna vaccine in January 2022.[5]

In the U.S., approximately 69 percent of the population have completed a primary series; approximately 70 percent of Floridians have completed a primary series.[6] It is estimated that 16.5 percent[7] of Florida's population and 16.5 percent of the U.S. population[8] have had an updated (bivalent) booster dose.

COVID-19 Treatments

The U.S. Food and Drug Administration (FDA) approves medications for use following a review of clinical data on safety and effectiveness. In instances of public health emergency, the FDA also issues Emergency Use Authorizations (EUAs) for the use of medical countermeasures; both new drugs not fully approved by the FDA, or existing drugs not approved by the FDA for this specific purpose.[9]

Since 2020, the FDA issued both approvals and EUAs for medications to treat COVID-19, listed in the table below.[10]

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[1] U.S. Food and Drug Administration, *Emergency Use Authorization,* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited Nov. 8, 2021). Medical countermeasures are FDA-regulated products (biologics, drugs, and devices) that may be used in the event of a public health emergency. A determination that a public health emergency exists is insufficient to enable the FDA to issue EUAs; *See* 21 U.S.C. § 360bbb-3; EUA allows the FDA to facilitate the availability and use of medical countermeasures during public health emergencies.
[2] U.S. Centers for Disease Control and Prevention, How CDC Is Making COVID-19 Vaccine Recommendations | CDC (last visited Nov. 11, 2021)
[3] U.S. Food and Drug Administration, Janssen COVID-19 Vaccine | FDA (last visited April 5, 2023).
[4] U.S. Food and Drug Administration, FDA Approves First COVID-19 Vaccine | FDA (last visited April 5, 2023).
[5] Moderna COVID-19 Vaccines, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines, (last visited April 5, 2023).
[6] U.S. Centers for Disease Control and Prevention, *COVID Data Tracker, Daily Update for the United States,* https://covid.cdc.gov/covid-data-tracker/#datatracker-home, (last visited April 5, 2023); *See also COVID-19 Integrated County View, Vaccinations in Florida*, https://covid.cdc.gov/covid-data-tracker/#county-view?list_select_state=Florida&data-type=CommunityLevels, (last visited April 5, 2023).
[7] *Id.*
[8] U.S. Centers for Disease Control and Prevention, *COVID Data Tracker*, *COVID-19 Vaccinations in the United States,* https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-total
[9] U.S. Food and Drug Administration, *Emergency Use Authorization,* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited April 5, 2023). Medical countermeasures are FDA-regulated products (biologics, drugs, and devices) that may be used in the event of a public health emergency. A determination that a public health emergency exists is insufficient to enable the FDA to issue EUAs ; *See* 21 U.S.C. § 360bbb-3; EUA allows the FDA to facilitate the availability and use of medical countermeasures during public health emergencies.
[10] U.S. Food and Drug Administration, Coronavirus (COVID-19) Drugs, available at https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs#:~:text=Veklury%20(Remdesivir)%20is%20approved%20for,are%20at%20high%20risk%20for (last viewed April 1, 2023).

Drug	FDA Action	Use
Actemra (Tocilizumab)	Approved	Actemra (Tocilizumab) is approved for the treatment of COVID-19 in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Veklury (Remdesivir)	Approved	Veklury (Remdesivir) is approved for the treatment of COVID-19 in adults and pediatric patients (28 days of age and older and weighing at least 3 kilograms) with positive results of direct SARS-CoV-2 viral testing, who are: hospitalized, or not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.
Olumiant (baricitinib)	Approved	Olumiant (baricitinib) is approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Paxlovid (nirmatrelvir & ritonavir)	Emergency Use Authorization	Antiviral uses
Lagevrio (molnupiravir)	Emergency Use Authorization	Antiviral uses
Kineret (anakinra) (Immune Modulator)	Emergency Use Authorization	Kineret (anakinra) is authorized for the treatment of COVID-19 in hospitalized adults with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR).
Olumiant (baricitinib) (Immune Modulator)	Emergency Use Authorization	Olumiant (baricitinib) is authorized for the treatment of COVID-19 in pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygen (ECMO).
Actemra (tocilizumab) (Immune modulator)	Emergency Use Authorization	Actemra (tocilizumab) is authorized for the treatment of COVID-19 in hospitalized pediatric patients 2 to less than 18 years of age who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
REGEN-COV (casirivimab & imdevimab) SARS-COV-2-targeting Monoclonal Antibodies	Emergency Use Authorization	ARS-COV-2-targeting monoclonal antibodies (mAbs) are laboratory-produced antibodies that can help the immune system's attack on SARS-COV-2. These mAbs block entry into human cells, thus neutralizing the virus like other infectious organisms, SARS-CoV-2 can mutate over time, resulting in genetic variation in the population of circulating viral strains. Some variants can cause resistance to one or more of the mAb therapies authorized to treat COVID-19. Due to the high frequency of variants circulating within the United States that are not susceptible to the following mAbs, this product is not currently authorized in any U.S. region until further notice by FDA and may not be administered for the pre-exposure prophylaxis for prevention or the treatment of COVID-19 under the EUA.
Sotrovimab SARS-COV-2-targeting Monoclonal Antibodies	Emergency Use Authorization	ARS-COV-2-targeting monoclonal antibodies (mAbs) are laboratory-produced antibodies that can help the immune system's attack on SARS-COV-2. These mAbs block entry into human cells, thus neutralizing the virus like other infectious organisms, SARS-CoV-2 can mutate over time, resulting in genetic variation in the population of circulating viral strains. Some variants can cause resistance to one or more of the mAb therapies authorized to treat COVID-19. Due to the high frequency of variants circulating within the United States that are not susceptible to the following mAbs, this product is not currently authorized in any U.S. region until further notice by FDA and may not be administered for the pre-exposure prophylaxis for prevention or the treatment of COVID-19 under the EUA.
Bamlanivimab & Etesevimab SARS-COV-2-targeting Monoclonal Antibodies	Emergency Use Authorization	ARS-COV-2-targeting monoclonal antibodies (mAbs) are laboratory-produced antibodies that can help the immune system's attack on SARS-COV-2. These mAbs block entry into human cells, thus neutralizing the virus like other infectious organisms, SARS-CoV-2 can mutate over time, resulting in genetic variation in the population of circulating viral strains. Some variants can cause resistance to one or more of the mAb therapies authorized to treat COVID-19. Due to the high frequency of variants circulating within the United States that are not susceptible to the following mAbs, this product is not currently authorized in any U.S. region until further notice by FDA and may not be administered for the pre-exposure prophylaxis for prevention or the treatment of COVID-19 under the EUA.

Bebtelovimab SARS-COV-2-targeting Monoclonal Antibodies	Emergency Use Authorization	ARS-COV-2-targeting monoclonal antibodies (mAbs) are laboratory-produced antibodies that can help the immune system's attack on SARS-COV-2. These mAbs block entry into human cells, thus neutralizing the virus like other infectious organisms, SARS-CoV-2 can mutate over time, resulting in genetic variation in the population of circulating viral strains. Some variants can cause resistance to one or more of the mAb therapies authorized to treat COVID-19. Due to the high frequency of variants circulating within the United States that are not susceptible to the following mAbs, this product is not currently authorized in any U.S. region until further notice by FDA and may not be administered for the pre-exposure prophylaxis for prevention or the treatment of COVID-19 under the EUA.
Evusheld (tixagevimab co-packaged with cilgavimab) SARS-COV-2-targeting Monoclonal Antibodies	Emergency Use Authorization	ARS-COV-2-targeting monoclonal antibodies (mAbs) are laboratory-produced antibodies that can help the immune system's attack on SARS-COV-2. These mAbs block entry into human cells, thus neutralizing the virus like other infectious organisms, SARS-CoV-2 can mutate over time, resulting in genetic variation in the population of circulating viral strains. Some variants can cause resistance to one or more of the mAb therapies authorized to treat COVID-19. Due to the high frequency of variants circulating within the United States that are not susceptible to the following mAbs, this product is not currently authorized in any U.S. region until further notice by FDA and may not be administered for the pre-exposure prophylaxis for prevention or the treatment of COVID-19 under the EUA.
Propofol-Lipuro 1% (Sedative)	Emergency Use Authorization	Maintains sedation, generally via continuous intravenous infusion, in patients who are intubated and require mechanical ventilation in an intensive care unit (ICU) setting.
Regiocit (Renal replacement therapy)	Emergency Use Authorization	Continuous renal replacement therapy (CRRT) is a type of "dialysis," which is a machine treatment that filters and purifies the blood when a patient's kidneys are damaged or are not functioning normally. CRRT is used for patients with kidney injury in acute care settings.
Fresenius Medical multiFiltrate/multi Bic/multiPlus (Renal replacement therapy)	Emergency Use Authorization	Continuous renal replacement therapy (CRRT) is a type of "dialysis," which is a machine treatment that filters and purifies the blood when a patient's kidneys are damaged or are not functioning normally. CRRT is used for patients with kidney injury in acute care settings.

Some practitioners and patients advocate for the use of other drug and non-drug remedies to treat COVID-19, with or without the use of the above FDA-approved or -authorized drugs, including, for example:

- Hydroxychloroquine[11]
- Ivermectin[12]
- Methanol
- Herbal medicines
- Vitamins
- Minerals
- Probiotics
- Nasal saline irrigation and gargling
- Ultraviolet light
- Green tea
- Elderberry syrup
- Ginger

Federal Vaccination and Prevention Requirements

In addition to approving vaccines and treatments, the federal government adopted policies to require vaccination and other preventive measures for businesses and health care facilities.

[11] See, U.S. Food and Drug Administration, "FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems", Jan. 12, 2022, available at https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or (last viewed April 1, 2023).

[12] See, U.S. Food and Drug Administration, "FAQ: COVID-19 and Ivermectin Intended for Animals", current as of March 10, 2023, available at https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals#:~:text=A%3A%20No.,acquired%20from%20a%20legitimate%20source (last viewed April 1, 2023).

OSHA COVID-19 Emergency Temporary Standards

On November 4, 2021, the federal Occupational Safety and Health Administration (OSHA) issued "COVID-19 Vaccination and Testing; Emergency Temporary Standards" (OSHA ETS), along with a number of Fact Sheets, FAQs, and templates for a mandatory vaccination policy, and a vaccination, testing, and face covering policy. The OSHA ETS was published in the Federal Register on November 5, 2021. [13]

In summary, the OSHA ETS required all employers with 100 or more employees to ensure their workforce is fully vaccinated or require any workers who remain unvaccinated to produce a negative test result at least weekly and wear a mask. These employers are also required to provide paid time off to workers who decide to be vaccinated so they can recover in the event of experiencing any short-term side effects from the vaccination. The OSHA ETS provides penalties of up to $14,000 per violation. According to the Administration, the requirement was expected to impact over 80 million workers in private sector businesses with 100 or more employees.[14]

Challenges to the new OSHA ETS and applications for a stay on its enforcement were brought in almost every federal circuit in the US. On November 6, 2021, a panel of the US Court of Appeal for the Fifth Circuit granted a nationwide stay of the OSHA ETS pending further action of that court, because the "petitions give cause to believe there are grave statutory and constitutional issues with the mandate." On November 12th, the Fifth Circuit reaffirmed the initial stay finding that the OSHA ETS was "overbroad" and "flawed," and determined that it exceeded OSHA's statutory authority.[15]

All the cases were consolidated and transferred to the Sixth Circuit Court of Appeal,[16] which has the authority to modify, rescind, or leave in place the stay issued by the Fifth Circuit.[17] As of April, 2023, OSHA has withdrawn the vaccination and testing ETS as an enforceable emergency temporary standard and suspended enforcement and implementation activities regarding the ETS pending further development in the litigation.[18]

CMS Vaccination Rule

On November 5, 2021, CMS issued a new regulation (CMS Rule)[19] governing Medicare certification and Medicaid provider enrollment. As a condition of receiving Medicare and Medicaid funds, health care providers must establish and implement policies that will ensure that all workers are fully vaccinated[20] against COVID-19.[21] In 2022, CMS revised its guidance and survey procedures for all provider types related to assessing and maintaining compliance with the staff vaccination

[13] COVID–19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61402, https://www.federalregister.gov/d/2021-23643

[14] The White House, *Path Out of the Pandemic: President Biden's COVID-19 Action Plan*, (Sep. 2021), https://www.vsba.org/wp-content/uploads/2021/09/Path-out-of-the-Pandemic-POTUS-COVID-19-Action-Plan.pdf (last visited April 5, 2023).

[15] National Law Review, *Fifth Circuit Hits Pause on OSHA COVID-19 Vaccine or Testing Emergency Standard,* https://www.natlawreview.com/article/fifth-circuit-hits-pause-osha-covid-19-vaccine-or-testing-emergency-standard

[16] The 6th Circuit hears cases from federal district courts in Kentucky, Michigan, Ohio, and Tennessee.

[17] Consolidation Order, *In Re: Occupational Safety and Health Agency, Interim Final Rule: COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61402, Issued On November 4, 2021* , MCP No. 165, J.P.M.L. (November 16, 2021).

[18] U.S. Dept. of Labor, OSHA, *COVID-19 Vaccination and Testing ETS*, January 25, 2022, https://www.osha.gov/coronavirus/ets2, (last visited April 5, 2023); See Also, JDSupra, *Navigating the Uncertainties of the ETS: What Employers Should Do Now,* https://www.jdsupra.com/legalnews/navigating-the-uncertainties-of-the-ets-4266782/ (last visited April 5, 2023).

[19] The regulation was issued as an Interim Final Rule. Under Medicare law, Interim Final Rules expire three years after issuance , unless finalized. The Interim Final Rule was effective on the day of publication in the Federal Register (Nov. 5, 2021). *See*, Social Security Act § 1871(a)(3) (42 U.S.C. § 1395hh(a)(3)).

[20] "Fully vaccinated" means a person 14 days after receipt of either a single-dose vaccine or the second of a two-dose vaccinations sequence. Receiving a booster is not required to be considered "fully vaccinated." 61563, citing Centers for Disease Control and Prevention, *Frequently Asked Questions about COVID-19 Vaccination,* , Mar. 29, 2023, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html, (lastvisited April 5, 2023).

regulatory requirements. The revisions address frequency of review of the staff vaccination requirements to ensure that deficiency citations recognize good faith efforts by providers/suppliers.[22] CMS estimated the rule would apply to 13,050,000 health care staff in the first year, nationwide.[23]

State survey agencies conduct provider surveys to ensure compliance with CMS regulations; in Florida, federal enforcement surveys are conducted by the Agency for Health Care Administration.

On November 10, 2021, ten states[24] filed a lawsuit in federal court challenging the CMS rule. The states argue the rule violates the federal Administrative Procedure Act, is not authorized by Congress, and violates Medicare laws requiring consultation with state officials prior to issuing certain types of rules. The states also make constitutional claims related to spending powers, the anti-commandeering doctrine and the Tenth Amendment, and requested declaratory and injunctive relief.[25] The court granted the plaintiffs' request for expedited briefing, but a hearing date on the preliminary injunction has not yet been set.

On November 18, 2021, the State of Florida filed a lawsuit in the Northern District of Florida challenging the CMS Rule.[26] The state argues the CMS action:

- Exceeds its authority under federal law;
- Was issued without consulting the states as required under law;[27]
- Was issued without the notice and comment period required by law;
- Is arbitrary and capricious; and
- Is a condition of receiving federal funds which violates the Spending Clause of the U.S. Constitution.[28]

Florida requested the court issue a temporary restraining order and preliminary and permanent injunctive relief prohibiting defendants from enforcing the mandate which was denied for failure to make a showing of irreparable harm to justify such an order.[29]

On January 13, 2022, the U.S. Supreme Court upheld the validity of the CMS rule.[30] Thereafter, Florida moved to dismiss its appeal, and the case was terminated.[31]

In response to these federal actions, the Florida Legislature, in Special Session 2021-B, adopted legislation to regulate businesses, government entities and educational institutions related to requirements for vaccination, proof of vaccination or infection recovery, and the use of face masks. (See below.)

Vaccination Mandates in Florida

Private Businesses

Section 381.00317, F.S., generally prohibits businesses from requiring any employee or contracted worker to be vaccinated for COVID-19. This prohibition applies to any form of corporation, partnership,

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[21] Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555 to 61627 (Nov. 5, 2021) (to be codified at 42 C.F.R. pts. 416, 418, 441, 460, 482-486, 491, and 494), available at 2021-23831.pdf (govinfo.gov) (last visited April 5, 2023).
[22] Centers for Medicare & Medicaid Services, Memorandum, *Revised Guidance for Staff Vaccination Requirements*, https://www.cms.gov/files/document/qs0-23-02-all.pdf, Oct. 26, 2022, (last visited April 5, 2023).
[23] Health Care Staff Vaccination, 86 Fed. Reg. 61603, Table 6.
[24] Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, New Hampshire.
[25] *Missouri, et al, v. Joseph Biden, Jr., et al*, No. 21-01329, (E.D. Missouri filed on Nov. 10, 2021).
[26] *Florida v. Dep't. of Health and Human Srvcs., et al.*, No. 21-2722 (N.D. Fla. filed on November 17, 2021).
[27] 42 U.S.C. s. 1395z
[28] U.S. Const. art. I, s. 8
[29] *Florida v. Dep't. of Health and Human Srvcs., et al*., No. 21-2722 (N.D. Fla.) (See Order denying Motion for Preliminary Injunction, November 20, 2021).
[30] *Biden. v. Missouri,* 142 S.Ct. 647 (2022).
[31] *Florida v. Dep't. of Health and Human Srvcs., et al.* No. 21- 2722 (N.D. Fla.) *(See* Notice of Voluntary Dismissal by State of Florida, February 4, 2022).

association, cooperative, joint venture, business trust, or sole proprietorship that conducts business in this state, and any charitable organization.

Businesses can require employee vaccination, if they allow the employees to opt out of vaccination for these or any other reasons:

- for medical or religious reasons;
- based on immunity to COVID-19 (as determined by testing methods set by DOH rule);
- if the employee agrees to periodic testing; or
- if the employee uses employer-provided personal protective equipment (PPE).

The statute lays out specific criteria for claiming each of the above exemptions, and requires employer to use DOH forms for employees to submit statements of exemption.

This prohibition is enforced by the Department of Legal Affairs (DLA) within the Office of the Attorney General. Employees may file complaints with DLA, which investigates them. DLA must offer the employer the opportunity to comply with the law. However, DLA is required to fine an employer who violates this prohibition and terminates an employee due to a vaccination mandate: up to $10,000 per violation for employers with under 100 employees; and up to $50,000 per violation for employers with 100 or more employees. The statute authorizes the Attorney General to consider various factors and mitigating circumstances when determining the amount of the fine.

An employer can avoid fines by reinstating employee back pay, if accomplished prior to the issuance of a final order.

In addition, an employee terminated for failure to comply with an employer vaccination mandate is eligible for reemployment assistance under ch. 443, F.S., and that refusal to comply does not disqualify the employee based on misconduct.[32]

Section 381.00318, F.S., provides a public records exemption for information related to vaccination mandate investigation of a private business. All such information is both confidential and exempt from disclosure during an active investigation, and remains so when the investigation is no longer active if the disclosure, as determined by the Attorney General, would jeopardize another, active, investigation, or result in certain harms to the complaining employee.

Since enactment, DLA has received 927 complaints, the majority of which were closed due to lack of a statutory violation. DLA found probable cause for nine complaints, and filed a single administrative complaint against an employer.[33]

Government Entities and Educational Institutions

Section 112.0441 prohibits governmental entities and educational institutions from requiring any employee or contracted worker to be vaccinated for COVID-19. This prohibition applies to the state and any political subdivision of the state, including local governments, boards and commissions; and to schools governed by school districts, charter schools, state universities, state college system

[32] The Federal-State Unemployment Insurance Program provides unemployment benefits to eligible workers unemployed through no fault of their own, as determined by state law. The program is administered as a partnership between the federal government and the states. Florida's program, administered by the Department of Economic Opportunity (DEO) under ch. 443, F.S., requires claimants to meet certain eligibility criteria. Applications may be disqualified if the employee:

- Voluntarily left work without good cause attributable to his or her employer;
- Has been discharged by his or her employer for misconduct;
- Is unemployed due to a suspension for misconduct connected to his or her work;
- Is unemployed due to a leave of absence initiated by the individual; or
- Is discharged for misconduct connected with the individual's work, consisting of drug use, confirmed by a positive drug test
- Failed without good cause to apply for available suitable work, accept suitable work when offered to him or her, or return to his or her customary self-employment when directed by DEO.

[33] Department of Legal Affairs, email to committee staff from Libby Guzzo, Legislative Affairs Director, Feb. 7, 2023 (on file with committee staff).

institutions, developmental research schools, the Florida Virtual School and the Florida School for the Deaf and Blind.

The Department of Health (DOH) enforces this prohibition: current law authorizes DOH to impose a fine up to $5,000 per violation. In addition, an employee terminated for failure to comply with an employer vaccination mandate is eligible for reemployment assistance under ch. 443, F.S.

Similarly, s. 381.00319, F.S., prohibits educational institutions from requiring students to be vaccinated. Unlike the other vaccination mandate prohibitions, this prohibition is not enforced by any state agency. Instead, the law establishes a cause of action for adult students, or parents of minor students, to obtain injunctive relief against the educational institution. If the parent or student prevails, the law requires the court to award attorney fees and court costs to the plaintiff.

Sections 381.00317, 112.0441 and 381.00319, F.S., expire on June 1, 2023, unless saved by the Legislature, thereby ending these prohibitions on COVID-19 vaccination mandates by private businesses, governmental entities and educational institutions.

Documentation of Vaccination or Post-Infection Recovery

Private Businesses, Government Entities and Educational Institutions

Section 381.00316, F.S., prohibits private businesses, government entities and educational institutions from requiring people to provide documentation certifying COVID-19 vaccination or post-infection recovery to access the business, governmental operations or school attendance or enrollment, or to access the institution and its services.

Current law does not prohibit the use of screening protocols, and expressly states that it should not be construed to restrict businesses, governments and educational institutions from using protocols, if used in a manner consistent with "authoritative or controlling" government guidance.

DOH enforces this prohibition: current law authorizes DOH to impose a fine up to $5,000 per violation.

DOH received a combined total of 4,396 notifications of potential violations since enactment of the prohibitions on vaccination mandates and requirements for documentation of vaccination or post-infection recovery, as follows:

- Business Entities – 3,216
- Governmental Entities – 174
- Educational Institutions – 231
- Other (not specific) – 775

DOH issued 14 warning letters and 5 Notices of Violation, resulting in collection of two fines.[34]

Masks and Quarantine or Isolation

Schools

Section 1002.20(2)(n), F.S., prohibits K-12 public schools from requiring students to wear face masks or other facial coverings at school, other than when necessary for occupational or laboratory safety. Students are allowed to wear face masks if their parents allow it.

Current law also prohibits K-12 public schools from requiring students and employees to stay home from school if exposed to COVID-19, if they are asymptomatic and have not tested positive for COVID-19.

[34] Department of Health, email from Gangul Gabadage, April 5, 2023, on file with committee staff.

As with the student vaccination law, this prohibition is enforced by civil litigation, rather than by a state agency. Parents and adult students may bring an action for declaratory and injunctive relief against the school district for violations; and, if they prevail, will be awarded attorney fees and costs.

Section 1002.20(2)(n), F.S., expires on June 1, 2023, unless saved by the Legislature, thereby ending this prohibition on mask requirements and COVID-19 quarantine requirements by private businesses, public K-12 schools.

Private Businesses and Government Entities

Current law does not address mask or quarantine requirements by other (non-educational) government entities, or by private businesses.

Effect of the Bill

The CS/HB 1013 significantly expands regulation of COVID-19-related policies for private businesses, governmental entities and educational institutions.

COVID-19 Tests, Facial Coverings, Vaccination Status and Post-Infection Recovery Status

Businesses and Governments

The bill amends s. 381.0016, F.S., to add prohibitions for private businesses and government entities on requiring any person to take a COVID-19 test to gain entry to, or services from, the business or government entity, or as a condition of contracting with, employing, or promoting, anyone.

Similarly, the bill adds prohibitions for private businesses and government entities on requirements to wear a facial covering, including a cloth or surgical face mask, a face shield, or any other device that covers the mouth and nose. This prohibition does not apply to health care providers and practitioners, if they are in compliance with facial covering prohibitions and regulations elsewhere in the bill (see below).

In addition, the bill prohibits businesses and governments from discriminating against employees or applicants for employment, or otherwise discriminate against any person, based COVID-19 vaccination, post-infection recovery status, or failure to take a COVID-19 test.

The bill requires DLA to enforce these new prohibitions, and enforce the current prohibition on requiring documentation of COVID-19 vaccination or post-infection recovery (which is currently enforced by DOH). The DLA may impose an administrative fine up to $5,000 for each violation, which revenues must be deposited into the General Revenue Fund, consistent with the enforcement provisions in current law. The bill authorizes DLA to take certain administrative actions when investigating a complaint of a violation of these provisions, such as administering oaths, taking depositions, conducting inspections, issuing subpoenas, etc.

Consistent with current law, the bill authorizes reemployment assistance under ch. 443, F.S., for an employee terminated for failure to comply with prohibited mandates.

Educational Institutions

The bill amends s. 381.0016, F.S., to add prohibitions for educational institutions on requiring any person to take a COVID-19 test to gain access to, or services from, the educational institution. Similarly, the bill adds a prohibition on requirements to wear a facial covering, including a cloth or surgical face mask, a face shield, or any other device that covers the mouth and nose. This prohibition does not apply to facial covering requirements necessary for classes with occupational or laboratory safety requirements.

The bill prohibits educational institutions from discriminating against any person based on based COVID-19 vaccination, post-infection recovery status, failure to take a COVID-19 test or wear a facial covering.

The bill requires DOH to enforce these new prohibitions, and enforce the current prohibition on requiring documentation of COVID-19 vaccination or post-infection recovery, consistent with the enforcement provision in current law. The DOH may impose an administrative fine up to $5,000 for each violation, which revenues must be deposited into the General Revenue Fund, consistent with the enforcement provisions in current law. The bill authorizes DOH to take certain administrative actions when investigating a complaint of a violation of these provisions, such as administering oaths, taking depositions, conducting inspections, issuing subpoenas, etc.

The bill repeals the current enforcement provision for violations of the COVID-19 vaccination or post-infection recovery documentation prohibition. Under the bill, parents (and adult children) will no longer be expressly authorized to bring an action against the educational institution for declaratory and injunctive relief.

The bill does not save s. 381.00317, F.S., or s. 112.0441, F.S., from repeal, so the current law prohibitions against private businesses and government entities requiring employee vaccination will terminate on that date.

Facial Coverings and Health Care Facilities

The bill creates s. 408.833, F.S., to address facial covering requirements in health care facilities.

First, it requires the Agency for Health Care Administration (AHCA) and DOH to jointly develop standards for facial coverings for infection control in health care settings, and adopt them in the form of emergency rules by July 1, 2023, and publish the standards on their websites. The bill exempts the agencies from current law making emergency rules effective for only 90 days, and provides that the emergency rules will remain in effect until the agencies adopt rules under the non-emergency procedures of ch. 120.

Second, the bill prohibits health care providers and practitioners from requiring facial coverings inconsistent with the AHCA/DOH standards. This applies to all health care practitioners and health care settings regulated by DOH and its boards, to facilities licensed by AHCA, certain AHCA-regulated health care clinics exempt from regulation, and certain providers regulated by the Agency for Persons with Disabilities.

Instead, the bill requires health care providers and practitioners to adopt facial covering policies and procedures based on the AHCA/DOH standards by August 1, 2023, publish them online, and post them in their offices or facilities.

The bill makes violations of this provision grounds for licensure discipline under the applicable practice acts or facility licensure acts.

<u>COVID-19 Treatment Alternatives</u>

The bill creates s. 456.62, F.S., to regulate interactions between practitioners and patients diagnosed with COVID-19 related to treatment medication decisions.

Heath care practitioners must obtain informed consent from the patient (or the patient's legal representative) before prescribing medication to treat COVID-19. The practitioner must explain the "alternative medications" to treat COVID-19, including the benefits and risks, sufficiently to allow the patient to make a "prudent" decision, taking into account the patient's physical state and ability to understand the information.

The bill does not define "alternative medications"; instead, it requires the practitioner to consider medications currently authorized or approved by the federal Food and Drug Administration (see table above, pp. 3-4). The practitioner must use best clinical judgment to identify, among those alternatives, which would benefit the patient.

The bill creates s. 395.1057, F.S., to establish a patient right to choose COVID-19 treatment alternatives in a hospital, and prohibits hospitals from interfering with that right, if the treatment is recommended by a health care practitioner with privileges at that hospital. Interference with the patient's right is grounds for discipline under the hospital licensure act.

Current law related to pharmacy practice obligates pharmacies to exercise independent professional judgment when dispensing a prescription. The bill grants license disciplinary immunity to a pharmacist when properly dispensing a COVID-19 treatment alternative.

The bill provides an effective date of June 1, 2023.

B. SECTION DIRECTORY:

Section 1: Amending s. 381.00316, F.S., relating to discrimination based on COVID-19 vaccination or recovery status; refusal to wear a facial covering; COVID-19 test.
Section 2: Amending s. 381.00319, F.S., relating to prohibition on facial covering and COVID-19 vaccination and testing mandates
Section 3: Creating s. 395.1057, F.S., relating to patients' rights to choose COVID-19 treatment alternatives.
Section 4: Creating s. 408.833, F.S. relating to facial covering requirements in health care facilities.
Section 5: Creating s. 456.62, relating to communication of COVID-19 treatment alternatives.
Section 6: Amending s. 465.0266, F.S., relating to common database.
Section 7: Providing an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   DOH and DLA may experience increased revenue from fines, which the bill requires to be deposited into the General Revenue Fund.

2. Expenditures:

   The Department of Legal Affairs (DLA) expended $519,758.77 in personnel costs to date enforcing the current law prohibition against vaccine mandates by private employers. DLA received 927 complaints, the majority of which were closed due to lack of a statutory violation. DLA found probable cause for nine complaints, and filed a single administrative complaint against an employer.[35] DLA estimates the need for an additional 6.2 FTE to implement the bill's provisions, totaling $275,080.99 in recurring general revenue, as indicated in the table below.[36]

[35] Department of Legal Affairs, email to committee staff from Libby Guzzo, Legislative Affairs Director, Feb. 7, 2023 (on file with committee staff).
[36] Department of Legal Affairs, Agency Bill Analysis of HB 1013, March 7, 2023. Note that this fiscal impact estimate is based on the bill as originally filed, and may require adjustment to accurately estimate the impact of the CS/HB content.

Class Code	Position Working Title	# FTE	Base Pay	Fringe Benefits	Total	% time spent	Estimated Cost
7747	Senior Assistant Attorney General	1.2	$94,786.69	$33,175.34	$127,962.03	100%	$153,554.44
	OPS Paralegal Specialist	2	$41,600.00	$12,480.00	$54,080.00	100%	$108,160.00
2117	Systems Programming Administrator-SES	1	$88,181.17	$30,863.41	$119,044.58	9%	$10,860.60
3128	Paralegal Specialist I	1	$38,000.04	$13,300.01	$51,300.05	1%	$569.47
3126	Legal Assistant III	1	$33,721.74	$11,802.61	$45,524.35	4%	$1,936.48
					Annual Cost		**$275,080.99**

As of April 11, DLA has 83 vacancies, so can address this need using existing positions. The Fiscal Year 2023-2024 House and Senate budgets both provide $5 million in nonrecurring General Revenue to DLA for COVID-related litigation, including the work required of DLA by this bill.[37]

Due to the potential increase of notifications and based on the number of complaints received during the implementation of the COVID-19 Vaccine Documentation Program, DOH projects a need for two positions at a professional level. The Department can initiate budget amendment actions during Fiscal Year 2023-2024 to address this need using existing positions.[38]

The bill provisions related to AHCA enforcement of the patients' right to choose COVID-19 treatment alternatives in hospitals has no fiscal impact on AHCA.

The bill provisions requiring AHCA and DOH to establish emergency rules has an insignificant negative impact on those agencies, which can be absorbed within current resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

[37] House Fiscal Year 2023-2024 GAA Section 82, reverting and appropriating the unexpended funds for Fiscal Year 2022-2023 for COVID-19 related litigation.
[38] Department of Health, Agency Bill Analysis for HB 1013, April 5, 2023.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill and current law provide DLA, DOH and AHCA sufficient rule-making authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES