

# Legal Lens

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## F.D.A. MOVES TO MAKE SOME HEARING AIDS AVAILABLE WITHOUT A PRESCRIPTION

Emily Anthes, *The New York Times*, October 19, 2021, <https://www.nytimes.com/2021/10/19/health/hearing-aid-fda.html>

Over 37 million American adults have a hearing impairment, but the majority do not use hearing aids. The Food and Drug Administration proposed a rule to allow hearing aids to be available without a medical exam, prescription or fitting. This rule, if passed, would allow for a new category of over-the-counter hearing aids that could improve access for millions. Costs have been attributed to one of the three reasons many with hearing loss take up to seven years before addressing the issues. Allowing for over-the-counter would decrease costs accumulated by prescriptions and audiologist visits. Currently, hearing aids can run anywhere from \$3,000-10,000 for a pair and regulations require visiting an audiologist or technician to be tested and fitted, which is not always covered by health insurance. Originally, in 2017 Congress passed the Over-the-Counter Hearing Aid Act which included

the FDA should issue draft legislation for nonprescription hearing aids by August 2020, but this did not occur due to the pandemic. In 2021, President Biden issued an executive order that the FDA must draft a rule and issue it by November 2021. The rule should encourage competition and drive prices down to make a pair available for a few hundred dollars. The rule has been published and the public can comment on the new rule for 90 days.

## MEDICARE OVERPAYMENTS RULING HITS INSURERS' FRAUD DEFENSES

Stuart I. Silverman, *Bloomberg Law*, August 25, 2021, [https://www.bloomberglaw.com/product/blaw/bloomberglawnews/health-law-and-business/X4INA1V4000000?bc=W1siU2VhcmNoICYgQnJvd3NlliwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWN0L2JsYXcvc2VhcmNoL3Jlc3VsdHMvZjdiYjBjZTU5ZmQ4NWRjMzA5M2MwZDY2OTNiMGY1NjliXV0-89be18e658a129b15a987fddd4c43ed0a1cad840&bn\\_news\\_filter=health-law-and-business&criteria\\_id=f77bb0ce59fd85dc3093c0d6693b0f562](https://www.bloomberglaw.com/product/blaw/bloomberglawnews/health-law-and-business/X4INA1V4000000?bc=W1siU2VhcmNoICYgQnJvd3NlliwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWN0L2JsYXcvc2VhcmNoL3Jlc3VsdHMvZjdiYjBjZTU5ZmQ4NWRjMzA5M2MwZDY2OTNiMGY1NjliXV0-89be18e658a129b15a987fddd4c43ed0a1cad840&bn_news_filter=health-law-and-business&criteria_id=f77bb0ce59fd85dc3093c0d6693b0f562)

The U.S. Court of Appeals for the District of Columbia Circuit held the Centers for Medicare and Medicaid overpayment rule was a valid use of statutory authority. CMS issued a rule that required Medicare Advantage plans to report and refund overpayment within 60 days if the insurer finds an overpayment based on an unsupported diagnosis. If an insurer failed to do so, they would be liable under the False Claims Act. UnitedHealthcare brought the suit against CMS challenging the rule. UnitedHealthcare asserted the rule should be based on “actuarial equivalence” as is used by the statute for setting

the monthly per-capita rates for Medicare Advantage plans. However, the Court found this does not apply to the insurer's obligation to refund identified overpayments. Beyond overpayment refunds, the False Claims Amendments Act of 2021 would impose higher burdens of proof of defendants when rebutting the materiality of a claim to prove a lack of materiality with "clear and convincing evidence."

## FEDERAL AUDITS OF TELEHEALTH TO SHAPE ITS POST-PANDEMIC FUTURE

Christopher Brown, *Bloomberg Law*, September 8, 2021, [https://www.bloomberglaw.com/product/blaw/bloomberglawnews/health-law-and-business/X1L60B10000000?bc=W1siU2VhcmNoICYgQnJvd3NlIiwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWNOL2JsYXcvc2VhcmNoL3Jlc3VsdHMvOWU5ZDI4NGQ1ZTNINzc3NDc5YzYzZGJzJkMjQyNmEiXV0-48b4c6c52ab96b00f5888a030aece6378956d054&bna\\_news\\_filter=health-law-and-business&criteria\\_id=9e9d284d5e3e777479c37dbcf2d2426a](https://www.bloomberglaw.com/product/blaw/bloomberglawnews/health-law-and-business/X1L60B10000000?bc=W1siU2VhcmNoICYgQnJvd3NlIiwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWNOL2JsYXcvc2VhcmNoL3Jlc3VsdHMvOWU5ZDI4NGQ1ZTNINzc3NDc5YzYzZGJzJkMjQyNmEiXV0-48b4c6c52ab96b00f5888a030aece6378956d054&bna_news_filter=health-law-and-business&criteria_id=9e9d284d5e3e777479c37dbcf2d2426a)

During the pandemic, providers embraced telemedicine to continue providing care to patients who would have lost access due to COVID-19 restrictions and federal regulators had removed barriers to telehealth for Medicare and Medicaid. By April 2020, telehealth use accounted for almost one-third of outpatient encounters. Now, telehealth use has stabilized at 13-17% of encounters. Prior to the pandemic, Medicare limited telehealth coverage to rural areas, but temporary waivers on these limits to reimbursement allowed for the increase in telehealth usage during the pandemic. Most of these changes will expire with the public health emergency, so policy makers are starting to think about permanent coverage. However, recently the Justice Department and the Office

of Inspector General of the Department of Health and Human Services announced a \$4.5 billion health-care "takedown" of telemedicine companies. This audit is the first chance to truly analyze the integrity risks and appropriate safeguards for telehealth. The OIG plans to release the reports and policy recommendations later this year. The final goal is for CMS to use OIG recommendations to create appropriate guardrails for telehealth post-pandemic.

## WORKERS WITH UNVACCINATED SPOUSES WILL PAY MORE FOR INSURANCE, A LOUISIANA HEALTH SYSTEM SAYS

Kim Bellware, *Washington Post*, October 5, 2021, <https://www.washingtonpost.com/health/2021/10/05/unvaccinated-spouse-fee/>

Beginning in 2022, Ochsner Health System, Louisiana's largest health-care system, will require a \$200 monthly surcharge if an employee's spouse or domestic partner on the company health plan is not vaccinated against COVID-19. The CEO of Ochsner claims the policy is not a "mandate" as spouses and partners can opt out for health insurance elsewhere. Currently, Oschner has 33,000 employees and is one of the first large companies in the U.S. to create a policy that includes spouses and partners. Oschner, a self-insured company, spent \$9 million on covid care for individuals who were beneficiaries of their health plan in the past year. The mandate allows for health and religious exemptions but not all employees are accepting the mandate. On September 20, over 40 filed a lawsuit to block the mandate for violating medical privacy. Similar claims have been made against other organizations, like President Biden's vaccination

rules for all federal workers. According to Joel Friedman, surcharges are legal as long as exemptions are provided and are capped to a percentage of income. Louisiana has recently begun to see its highest infection rates since the start of the pandemic, with over 1,000 new cases a day. Only 45% of the eligible population in the state is fully vaccinated.

### ARIZONA AG EXPANDS LEGAL CHALLENGE TO BIDEN VACCINE MANDATES

Robert Iafolla, *Bloomberg Law News*, Oct. 22, 2021, [https://www.bloomberglaw.com/bloomberglawnews/daily-labor-report/X2TVT3T4000000?bna\\_news\\_filter=daily-labor-report#jcite](https://www.bloomberglaw.com/bloomberglawnews/daily-labor-report/X2TVT3T4000000?bna_news_filter=daily-labor-report#jcite)

Arizona Attorney General Mark Brnovich filed an amended complaint against the Biden Administration seeking to block a vaccine mandate for federal employees and contractors. The complaint alleges President Joe Biden both lacks authority to mandate vaccination and calls the mandate a constitutional violation. In his complaint, Brnovich also attacked the validity of mandating uptake of a vaccine approved under emergency-use authorization, though experts have said the argument has lost footing since the Pfizer vaccine received full FDA approval. He also made a connection in the complaint between immigration policies and the vaccine mandate, calling it discriminatory against citizens and immigrants with work visas, as undocumented immigrants would not be subject to the mandate. Brnovich called the mandate “one of the greatest infringements upon individual liberty, federalism, and the separation of powers by any administration in our country’s history” in a news release. The

recently filed amended complaint is triple the length of the first, which Brnovich filed in early September. The U.S. Justice Department declined to comment.

### NO PAPERS, NO CARE: DISABLED MIGRANTS SEEK HELP THROUGH LAWSUIT, ACTIVISM

Heidi de Marco, *Kaiser Health News*, Sept. 16, 2021, <https://khn.org/news/article/no-papers-no-care-disabled-migrants-seek-help-through-lawsuit-activism/>

A federal class action lawsuit filed in the U.S. District Court for the Central District of California alleges that U.S. Immigration and Customs Enforcement and the Department of Homeland Security has discriminated against detainees by failing to supply mental and physical health care. A September feature from *Kaiser Health News* detailed the lack of medical services available for undocumented immigrants, whether detained or simply living without papers in the U.S. Currently, those with asylum status have access to private health insurance on the Affordable Care Act marketplace, or, in some cases, can get public assistance. California’s Medicaid program MediCal pays for services for people 26 and under, regardless of immigration status. Beginning next spring, it will cover income-eligible undocumented people 50 and older. Though activists are celebrating the expanded eligibility, many have faced difficulty accessing necessary care. One 60-year-old undocumented woman living in Riverside, California became blind at 46 due to a rare genetic condition. Without legal status, she could not pay for her medical care. In detention, immigrants face even harsher conditions. The class action

lawsuit calls for improved conditions rather than monetary damages. The 15 plaintiffs, most of whom were released or deported, instead seek care including provision of wheelchairs and American Sign Language interpreters. Currently, there is little to no care for disabilities for immigrants held in detention, the lawsuit alleges. Neither ICE nor Homeland Security responded to requests for comment. The trial is set for April.

### **NEEDLE EXCHANGES ARE TARGETED BY ECO-ROOTED LAWSUITS. A NEW CALIFORNIA LAW WILL STOP THAT.**

Rachel Bluth, *Kaiser Health News*, Oct. 6, 2021, <https://khn.org/news/article/needle-exchanges-environmental-lawsuits-california-law-newsom/>

Opponents to needle exchanges are suing the programs using a new approach: under environmental regulations for causing pollution in parks and waterways. Though across California opponents have won against needle exchange programs, Gov. Gavin Newsom signed a bill in early October to put a stop to the practice. Still, the bill, drafted by physician and Assembly member Joaquin Arambula, comes after free needle exchange programs across the state had to stop or change their practices. Additionally, lawsuits challenging needle programs on other grounds can still prevail despite the state law. Meanwhile, some local ordinances have banned needle exchange programs altogether. The law will take effect on January 1, making it impossible to sue needle exchange programs under the California Environmental Quality Act, which generally applies to major construction projects. Needle exchange programs were created to curb the spread of certain communicable diseases, like HIV and hepatitis C. Opponents who have

sued under environmental laws include local officials, former law enforcement officers, and community groups. Research has, for decades, shown that needle exchange programs are not major contributors to pollution, and those who participate in those programs are more likely to properly dispose of used needles than those who don't.

### **MERCK WILL SHARE FORMULA FOR ITS COVID PILL WITH POOR COUNTRIES**

Stephanie Nolan, *The New York Times*, Oct. 27, 2021, <https://www.nytimes.com/2021/10/27/health/covid-pill-access-molnupiravir.html>

Merck has promised a royalty-free license for its Covid-19 pill that would allow poorer nations to manufacture the pill and sell it inexpensively. The news comes amid a vaccine shortage in many low-income countries. The agreement with nonprofit Medicines Patent Pool will provide sublicensing for the antiviral pill's formulation to 105 countries. The pill, called molnupiravir, will be manufactured mostly in Asian and African countries. Merck's own data shows the pill reduced hospitalizations and deaths due to Covid by fifty percent. It is awaiting regulatory approval. Treatment will cost \$20 for five days for the generic drug. Advocates supported Merck's unusual decision. It came after the company granted licenses to eight Indian drug makers, who they worried would not be able to make enough of it to support access in all low-income countries that could potentially benefit from it. Merck will assist in the technology transfer. Medicines Patent Pool director Charles Gore called the agreement "the first transparent public health license for a Covid medicine." Merck's licensing agreement specifically prohibits sales in middle income countries, like China and Russia. Merck

will instead continue to sell the drug at much higher prices in middle income countries. The agreement also excludes most countries in Latin America.

## RELIGIOUS HEALTHCARE PROVIDERS WIN INJUNCTION ON ACA RULES

The Associated Press, *Modern Healthcare*, Aug. 16, 2021, <https://www.modernhealthcare.com/legal/religious-healthcare-providers-win-injunction-aca-rules>

A federal district court judge in Texas permanently enjoined the Biden administration from interpreting the Affordable Care Act as requiring health care providers to provide certain treatment. Under the injunction, Judge Reed O'Connor, siding in favor of a Catholic health system and Christian medical association, ruled that the law could not be read to require religious providers to perform abortions or gender-transition treatment. The U.S. Department of Health and Human Services argued it does not currently require provision of

such procedures. O'Connor found basis for the injunction in an earlier ruling that found HHS had violated the Religious Freedom Restoration Act. A federal judge in North Dakota issued a similar decision last January, which the Biden administration is now appealing. The Texas lawsuit dates back to 2016, when the Obama administration's HHS issued the ACA-related rules. At the time, HHS interpreted its rules to show that, for example, health care institutions which provided hysterectomies would need to do so for transgender men. In 2019, O'Connor voided the rule language which barred discrimination based on gender identity or pregnancy termination. The Supreme Court ruled in 2020 that sex discrimination included discrimination based on gender identity, and in May, HHS said its rule interpretations would follow the Supreme Court's ruling while abiding by previous lower court rulings. O'Connor found HHS's position to be contradictory. ☩