And The Beat Goes On: Status of Litigation on CMS IFR and OSHA IFR

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We supplement our last four Health Care Law Alerts with this update of significant court decisions affecting health care providers attempting to chart a course on "shot-or-test" and vaccine mandates:

CMS INTERIM FINAL RULE (CMS IFR):

No Nationwide Injunction: In the latest move in the "[litigation] chess game," on December 15, the Fifth Circuit Court of Appeals dissolved the nationwide injunction against enforcement of the CMS IFR mandating vaccines for health care workers at certain Medicare/Medicaid-certified health care providers. The opinion by the three-judge panel found that a nationwide injunction impermissibly bound states not before the court, including those that might have chosen to follow the CMS IFR. The Fifth Circuit echoed the concerns against such injunctions expressed by Justice Gorsuch in *DHS v. New York*,[1] criticizing the Louisiana district court's failure to justify a nationwide injunction.

Where Are Injunctions in Place? For now, at least until the three-judge panel considering the appeal ultimately rules, the Fifth Circuit continued the stay against enforcement of the CMS IFR only in the 14 states that were parties in the lawsuit: **Arizona, Alabama, Georgia, Idaho, Indiana, Kentucky, Louisiana, Mississippi, Montana, Ohio, Oklahoma, South Carolina, Utah, and West Virginia.**

On December 14, in a 2-1 order with no opinion, the Eighth Circuit Court of Appeals rebuffed the Government's motion to dissolve the stay against enforcement of the CMS IFR in 10 other states while the Eighth Circuit considers the appeal. Those 10 states include: **Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming.**

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Note: briefing in that appeal continues well after the January 4 date in the CMS IFR: the Government's brief is due on January 10; the responding brief, on February 9. An opinion will issue after briefing and oral argument are completed.

For now, a health care provider and supplier covered by the CMS IFR in those 24 states may choose, but are not required, to adopt the mitigating measures for patient and staff safety in the CMS IFR, unless state law prohibits doing so.

What About the Other 26 States? In the other 26 states, including Michigan, recall that, as we pointed out in our December 14 Alert, CMS Directors notified their State Agency Directors by a December 2 Memo that CMS survey and enforcement of the CMS IFR would be suspended "while there are court-ordered injunctions in place prohibiting enforcement of this provision." CMS could take the position that it will enforce the CMS IFR in states where no injunction is in place. For example, in Florida, the Eleventh Circuit has held that the State of Florida did not justify its request for a preliminary injunction, as we noted in our prior Alert. For now, unless and until CMS states that it will continue to direct its surveyors not to find violations of the CMS IFR even in states where no injunctions are in place, covered health care providers and suppliers in those 26 states should comply with the mitigating measures and requirements in the CMS IFR, given the severe penalties for non-compliance.

Supreme Court Denials of Health Care Workers Emergency Motions: Added to this mix is Supreme Court action denying emergency motions by New York health care workers to invalidate New York's vaccine mandate because it allows no religious exemptions. Again, Justice Gorsuch wrote a dissenting opinion reaching the merits of the religious exemption issue.

OSHA IFR (Employers with 100 or more employees):

On December 15, the Sixth Circuit issued an order denying the petitioners' request to bypass a three-judge panel drawn from all 28 Sixth Circuit judges. Petitioners sought immediate review of the merits of the injunction showings by just the 16 active-status judges who participate on the En Banc Court. Less than a majority of those active judges voted for initial en banc review.

Two days later, on Friday December 17, the Sixth Circuit panel issued its opinion and dissolved the Fifth Circuit's stay against enforcement of the OSHA IFR. Two judges vacated the stay on the grounds that petitioners were unlikely to succeed on the merits of their arguments against enforcement and/or had only presented speculative harms from the OSHA IFR. The third dissented and would have enforced the stay.

The Sixth Circuit found that OSHA possessed the authority to issue the OSHA IFR and had met the "grave danger" and "necessity" requirements of the Occupational Safety and Health Act (the OSH Act). The court rejected the petitioners' argument that the OSH Act only permitted OSHA to address "occupational" infection and viruses in the workplace because the viruses could also be contracted outside of the workplace. The court deferred to the substantial research that OSHA had reviewed and analyzed before issuing its "shot-or-test" rule. The court rejected petitioners' arguments that OSHA's delay in promulgating the rule showed a lack of grave danger, finding instead that OSHA had

calibrated its response to changing circumstances, such as the possibility that FDA approval of vaccines beyond the earlier EUS (emergency use) approval could reduce vaccine hesitancy.

Within hours, a group of business trade associations applied for emergency review by the U S Supreme Court and asked to have the stay reinstated and OSHA prohibited from further action. In the wee hours of December 18, the states filed a similar application and asked the Court to review the merits of the case immediately.

OSHA issued the following statement announcing it is exercising enforcement discretion with respect to the compliance dates of the Emergency Temporary Standard on vaccination and testing:

"*To provide employers with sufficient time to come into compliance, OSHA will not issue citations for noncompliance with any requirements of the ETS before January 10 and will not issue citations for noncompliance with the standard's testing requirements before February 9, so long as an employer is exercising reasonable, good faith efforts to come into compliance with the standard. OSHA will work closely with the regulated community to provide compliance assistance.*"

ONE FINAL CONSIDERATION: AVAILABILITY OF FREE TESTS

As health care providers and suppliers consider mitigating measures for patient and staff safety, note that on December 2, the Biden Administration released a new 9-point plan to make available $2 billion in funds for free at-home testing for Americans eligible for vaccines and to require group health plans and health insurance issuers to reimburse for any testing costs. The administration's announcement notes:

"*To expand access and affordability of at-home COVID-19 tests, the Departments of Health and Human Services, Labor and the Treasury will issue guidance by January 15th to clarify that individuals who purchase OTC COVID-19 diagnostic tests will be able to seek reimbursement from their group health plan or health insurance issuer and have insurance cover the cost during the public health emergency.*"

More to come...

Note that the legal developments pertaining to the CMS IFR change almost daily. The accelerated nature of the cases and appeals means that healthcare providers should continue to monitor the situation closely.

Butzel will continue to track these cases, other litigation, the CMS position, and release of information on tests and insurance coverage. If you have any questions about the status and requirements of the CMS IFR, its impact on your health care facilities, and how to proceed in light of the injunctions and suspension of enforcement of the IFR, please contact the authors of this alert or any member of Butzel's health law, labor and employment law, and federal contractor law practices.

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[1] See our prior Alert: *resources-alerts-Part-I-Update-Where-Has-All-The-Litigation-Gone.html.*