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TOP TEN Issues in Health Law

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Health Review Committee ruled that a health care employer had violated OSHA's general duty clause by "failing to adequately address a workplace violence hazard—specifically, the risk of . . . employees being physically assaulted by a client with a history of violent behavior during a face-to-face meeting."[50] This decision may be an indication that OSHA is willing to take a broader view of the general duty clause where there is a "direct nexus between the work being performed by . . . employees and the alleged risk of workplace violence." This opinion may be particularly relevant to mental and behavioral health providers, home health providers, and others in the health care industry.

In addition to federal OSHA actions, certain states now require employers to implement workplace violence programs. Accrediting bodies also have weighed in on the importance of adequate protections against workplace violence for health care workers. In April 2018, The Joint Commission (TJC) issued a Sentinel Event Alert regarding physical and verbal violence against health care workers, and in doing so provided suggested actions and identified several TJC standards that relate to workplace violence.[51] Employers should expect to see continued efforts by OSHA, legislators, and accrediting bodies to prioritize this issue to better protect health care workers.

Sexual Harassment. In the wake of the #MeToo movement, state legislatures have begun addressing the issue of sexual harassment in the workplace. Several states have passed laws governing sexual harassment policies, trainings, and other practices in the workplace. Certain states also have challenged the legality of forced arbitration and/or non-disclosure requirements for sexual harassment claims. In 2020, we anticipate that additional state and local governments will pass laws intended to protect victims of sexual harassment in the workplace. Health care employers must be aware of the various laws in effect that impact them and take steps, both to ensure compliance and to protect their employees from harassment.

Wage and Hour. The U.S. Department of Labor's (DOL's) final overtime rule updating the salary basis test's earning threshold for exempt employees under the Fair Labor Standards Act (Final Rule) is effective January 1, 2020. The Final Rule increased the minimum salary that must be paid to professional, executive, administrative, and salaried computer employees, for those employees to be considered "exempt" from overtime requirements and established how adjustments to the new salary minimums will be made going forward.[52]

In light of the Final Rule, health care employers must identify exempt employees whose current salaries are less than the Final Rule's minimum salary thresholds and consider how to bring those employees' compensation into compliance—either by increasing their salaries to meet the Final Rule's salary levels, or by reclassifying those individuals as non-exempt and making them eligible for overtime. The DOL anticipates 1.3 million American workers will become newly eligible for overtime pay as a result of the Final Rule.

The DOL also published a final rule updating the regulations addressing the calculation of the regular rate of pay for overtime compensation under Section 7 of the FLSA.[53] This final rule is effective January 15, 2020.

Sexual Orientation and Gender Identity. On October 8, 2019, the Supreme Court of the United States heard three cases regarding whether Title VII of the Civil Rights Act prohibits discrimination on the basis of sexual orientation and/or gender identity. The outcome of these cases will have a significant impact on employers and employees, particularly in states that do not otherwise prohibit discrimination on the basis of sexual orientation or gender identity.

Conscience Rule. The HHS Office for Civil Rights issued the final Conscience Rule, which strengthens the conscience protections available to employees when those employees refuse to participate in certain services that they object to on religious or moral grounds.[54] As of this writing, the fate of the final rule is unclear. The rule triggered several legal challenges, and, shortly before the rule went into effect on November 22, 2019, federal courts in New York, Washington, and California vacated the final rule.[55]

The health care workplace continues to transform, due in part to states taking a more active role in areas that have traditionally been governed by federal law. The areas to watch identified above are merely examples of the myriad ways these state laws reshape the legal framework within which health care employers operate.

9 Medicaid Work Requirements

—Clifford Barnes, Epstein Becker & Green PC

On January 11, 2018, CMS issued a letter to State Medicaid Directors announcing that CMS would approve Section 1115 waivers where the states condition Medicaid participation on working in community engagement programs.[56] According to the letter, the rationale for such waivers is to support state demonstrations that test whether sustained employment or other productive community engagement leads to improved health outcomes.[57] Section 1115 of the Social Security Act permits states to experiment, test, and evaluate state specific policy changes and to waive state compliance with specific Medicaid requirements upon a determination that the state's innovative approach would still promote Medicaid objectives, the most important of which is to promote insurance coverage.[58]

The conflict between the purpose of the 1115 waiver program—experiments that still promote Medicaid program objectives—and the rationale for the work requirement—sustaining work to improve health outcomes—is playing out

in the courts, which have found a lack of evidence that the work requirement programs are promoting Medicaid objectives. All three decisions issued so far have determined that the HHS Secretary's waiver approval failed to adequately consider whether the proposed Medicaid innovative work requirement program in fact helped the state furnish health coverage. For example, in Kentucky, a federal court vacated the HHS approved waiver and remanded to HHS to correct its failure to consider how the waiver enhanced health coverage.[59] After further review by HHS and reimplementation by Kentucky, the waiver was again challenged with the same result as the first decision.[60] Court decisions also struck down work requirements in Arkansas and New Hampshire.[61] As of this writing, HHS has approved six states' work requirement programs but none have been implemented. Three states' work requirements have been set aside by the courts and nine states have filed applications that are pending.

As a general matter, states have applied the work requirement to diverse segments of the Medicaid population, including the Medicaid expansion population, the traditional Medicaid population, or both. Under the essential terms of the waivers, the applicable populations must meet the prescribed work requirements, which are typically described as some minimum number of hours of work per month, and the timely reporting of meeting the minimum. According to CMS, the work requirement is anchored in historic CMS principles that emphasize work to promote health and well-being.

Kentucky, one of the first states to have its work requirements approved by CMS, required both the expansion and the traditional Medicaid populations to timely report working 80 hours per month. However, less than two weeks after CMS' approval of Kentucky's Section 1115 waiver, 16 Medicaid enrollees and a state-wide class challenged the approval.[62] The U.S. District Court for the District of Columbia determined that the Secretary's waiver was arbitrary and capricious because it failed to adequately consider whether the new waiver program would actually help the state furnish medical assistance (health insurance) to its citizens, a central objective of Medicaid.

The court decisions setting aside work requirements in Arkansas, Kentucky, and New Hampshire reveal the same reasoning in each case—that CMS did not take into account the new waivers' effect on health coverage. According to a recent study by Harvard researchers, published in *The New England Journal of Medicine*, the implementation of the work requirement in Arkansas, the first state to implement the work requirement, increased uninsured rates, with thousands of adults who were the target of the policy losing insurance coverage in the six months after the requirements went into effect.[63] The study, which provides the first quantitative evidence of the work requirement, also found that employment rates of the target population did not increase with the new policy. In fact, according to the study, the vast majority of those affected by the requirement were employed or should have been exempted.

From a public policy prospective, the question is whether states can design work requirement programs that marry the Section 1115 waiver purpose of increasing health coverage and the CMS rationale of improving health. Some states, like Georgia, are proposing more tailored and nuanced approaches to avoid the legal problems that other states have faced. While the federal courts have shut down the current iteration of the work requirement programs, certain states are likely to continue to attempt to combine the waiver purpose and the CMS rationale. Please stay tuned!

10 The GDPR's Effect on Health Care Entities—*Christine Genaitis and Britton Nohe-Braun, Dentons US LLP*

The General Data Privacy Protection Regulation 2016/679 (GDPR), which went into effect in May 2018, seeks to regulate and standardize the collection, preservation, and use of personal data throughout the European Economic Area (EEA) as well as the transfer of that data to other jurisdictions. The GDPR applies to organizations "established" in the EEA that process "personal data" (regardless of whether the processing takes place within the EEA) and to organizations not "established" in the EEA that (1) offer goods or services to individuals in the EEA (even if no payment is required), or (2) monitor the behavior of individuals in the EEA.

The GDPR defines personal data as information relating to an identified or identifiable natural person, which is construed to include identifiers such as gender, age, date of birth, marital status, languages spoken, personal and corporate phone numbers and email addresses, corporate internal employee identification numbers, IP addresses, and cookies. Although anonymous data is not protected by the GDPR, pseudonymous data is protected because it is not fully anonymous.

Applicability to Health Care Entities. Health care entities should be cognizant of the fact that the GDPR provides extra protection for various "special categories" of personal data, which includes health data. This data may be processed only with the data subject's explicit consent or in specific circumstances, such as when (1) the data controller has employment law obligations or must bring or defend legal claims; (2) a substantial public interest necessitates the processing of the data; (3) the information is publicly available; (4) the information is needed for preventative or occupational medicine, public health, research, or statistical purposes; or (5) it is in the data subject's vital interest, such as when the data subject is unconscious and at risk of dying.

Health care entities should also ensure that any cross-border data transfers comply with the GDPR. Proper transfer methods include relying on adequacy decisions or utilizing appropriate safeguards, such as binding corporate rules, standard contractual clauses, approved codes of conduct or certification mechanisms, ad hoc contractual clauses, and international agreements.