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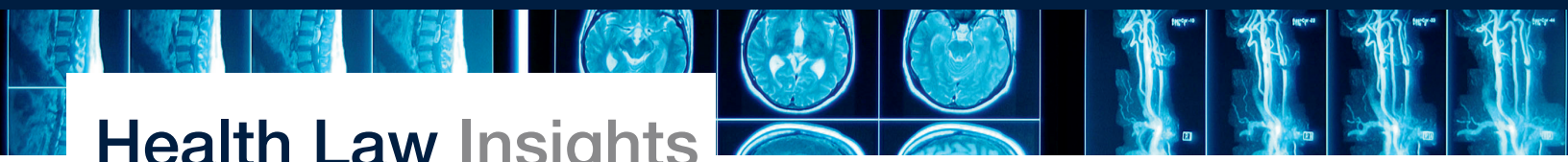

Health Law Insights

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NATIONAL

Drug Diversion Case Raises Red Flags for Hospitals Nationwide

A surgical technician who was discovered diverting drugs at a hospital in Denver and is suspected to have been diverting drugs at three prior hospitals from which he was terminated has tested positive for HIV according to federal prosecutors in Colorado. In a statement released on June 1, the U.S. Attorney's Office for the District of Colorado announced, "Blood testing released by consent of Rocky Allen has confirmed that federal defendant and former Swedish Medical Center of Colorado (Swedish) employee Rocky Allen carries HIV (subtype B) and that he is negative for Hepatitis B and C. Rocky Allen was a surgery technician at Swedish between August 2015 and January 2016. During his employment, he allegedly diverted fentanyl from the facility." The press release went on to note that Swedish had contacted 3,000 patients who were potentially impacted by Allen's action and that 2,500 had taken advantage of the free testing provided by the hospital. Five hundred patients still had not been tested as of the June 1 announcement.

A report by the Denver Post noted that Allen had been court-martialed for fentanyl theft while stationed in Afghanistan, yet managed to find employment at hospitals in Washington state, California and Arizona as a surgical technician. He was fired from each of those hospitals for drug diversion or suspected drug diversion before eventually finding employment at Swedish Medical Center last year. It is suspected that Allen was replacing syringes filled with fentanyl that were intended for hospital patients with dirty syringes that he had used on prior occasions and filled with saline solution. Allen, who in one instance was found passed out in the bathroom of a Phoenix hospital with an empty syringe in his hand, could have exposed as many as 5,000 patients to blood-borne pathogens at the various hospitals where he was employed since returning from Afghanistan.

The incident highlights a serious danger for hospitals in an environment that has seen an increasingly worsening opioid epidemic, both nationally and in New Jersey. Facilities that suspect a drug diversion has taken place are required under both state and federal law to act quickly and decisively upon receiving notice of the drug diversion. Notifications to authorities are required in a short time frame. Further, health care providers that discover a drug diversion should also be concerned with potential liability under the False Claims Act for overpayments in the form of reimbursement for drugs that were not provided in full to government health program beneficiaries.

Takeaways From the DOL's Final Overtime Pay Rule

On May 18, 2016, the U.S. Department of Labor (DOL) released its long-expected Final Rule, making certain significant changes to the executive, administrative and professional (EAP) exemption from overtime under the federal Fair Labor Standards Act. Changes were also made to the highly compensated executive exemption, but they are beyond the scope of this article. Although the Final Rule is not effective until December 1, 2016, employers should start preparing now for the overtime pay rule changes. Outlined below are the most significant takeaways from the DOL's Final Rule announcement:

- Doubling of Minimum Salary for EAP Exemption. The minimum salary threshold to qualify for the EAP exemption will increase from $23,660 ($455 per week) to $47,476 ($913 per week). Even if employees are paid salaries of more than $47,476, they still must meet the

duties and other tests to satisfy the particular exemption.

- Automatic Adjustments to the Minimum Salary Every Three Years. The Final Rule provides for adjusting the minimum salaries for the EAP exemption every three years, starting on January 1, 2020. The EAP minimum salary will be based on the annualized weekly earnings of the 40th percentile of full-time salaried workers in the lowest-wage U.S. Census region, which is currently the South.

- Certain Non-salary Pay May Be Used to Meet Salary Thresholds. The Final Rule provides employers some leeway to include certain nondiscretionary bonuses, incentive pay and commissions in employee compensation to meet the EAP salary threshold. Such payments must be made on a quarterly basis, and collectively they cannot exceed 10 percent of the salary threshold. The Final Rule also allows employers to make quarterly catch-up payments to meet the EAP salary threshold.

- No Changes to the Existing "Duties" Tests. The Final Rule is also significant for the change it did not make. The Final Rule does not modify the existing duties tests under the EAP exemption.

The Final Rule's effective date of December 1, 2016, gives employers ample lead time to prepare for the changes. Employers should immediately start gathering and analyzing information about employees classified as exempt – their compensation, hours worked, and their job duties and functions, particularly with respect to those jobs classified as exempt but paid less than the new minimum salary thresholds.

Having taken these steps, management will then be in a position to consider which of three general approaches makes the most sense in terms of controlling payroll and administrative burdens related to employees whose salaries are below the new minimum. These general approaches can be summarized as follows:

- Increase the employee's salary to the new minimum. As long as the employee is properly classified as exempt, this approach will minimize disruption and simply maintain the status quo. It should be considered for employees who are paid close to the new minimum, particularly those in high-income locations (e.g., New York City, Boston and Los Angeles) or high-income positions.

- Do nothing to an employee's current salary and forfeit the overtime exemption but control the amount of overtime the employee works. This approach requires caution but works best when the employee's weekly hours are relatively stable and are consistently at or less than 40 per week. Note that if a salaried, nonexempt employee works more than 40 hours in any given week, the employer will have to recalculate the employee's regular hourly rate and pay overtime for those hours. Employers will have to consider carefully whether such employees are accustomed to working "off the clock" or telecommuting and determine how to track or limit this "extra" work time.

- Convert the employee from salaried to hourly pay, creating overtime eligibility but at a reduced hourly rate that takes into account the hours per week the employee normally works. This approach is best (if not mandatory) for employees whose duties may not qualify them as exempt and who routinely work more than 40 hours per week. Done correctly, this approach can practically neutralize the fiscal effect of the new regulations. However, this approach will increase the administrative burden on employers, as they must track the time worked by such employees. In addition, employers must be mindful of the psychological impact of this change, as employees often associate a salaried, nonexempt position as indicative of a management-track job and greater status within the organization.

Rate of Uninsured Lowest Since 1997

In a reported published May 24, the National Center for Health Statistics released data from its National Health Interview Survey marking the lowest rate of uninsured adults in nearly two decades. The 2015 survey results found an uninsured rate of 12.8 percent for individuals aged 18 to 64 nationwide. Notably, the report tracked the uninsured rate for the same age cohort for 1997 through 2010 and observed an increase in the rate of uninsured. This trend, however, reversed itself in 2010, the year in which the Patient Protection and Affordable Care Act was enacted. During the five-year period of 2010 to 2015, the uninsured rate has steadily decreased from 22.3 percent in 2010 to the current level of nearly half that rate.

ER Docs Seek to Block Repayment Rule Under ACA

A national group representing emergency room physicians recently filed suit to prevent a minimum payment rule for emergency room physicians from going into effect. The lawsuit (*Am. Coll. of Emergency Physicians v. Burwell*), which was filed on May 12, 2016, in the U.S. District Court for the District of Columbia, focuses on a rule that was enacted by the Department of Health and Human Services, the Department of Transportation, and the Department of Labor under the Affordable Care Act (ACA) that requires insurers to pay certain minimum amounts for out-of-network emergency services. The rule, which applies only in those states that permit providers to charge patients for amounts above and beyond those paid by insurance, requires insurers to pay the highest of three metrics – the Medicare rate, the in-network rate or the usual, customary and reasonable amount (UCR) – for the emergency services provided.

The emergency room physician group claims that the rule doesn't take into account the fact that insurers can manipulate the UCR amount and thus cut into the provider's payment for out-of-network services. Insurance groups have pointed to the complaint as an example of physicians trying to force insurers and patients to pay excessive amounts for emergency services. The case demonstrates the tension that arises between providers and insurers amid a political and policy environment focused on affordability and cost savings.

Anti-Discrimination Rule Finalized by HHS

On May 13, the Office of Civil Rights (OCR) of the Department of Health and Human Services (HHS) issued the final rule implementing Section 1557 of the Affordable Care Act. The Final Rule, titled *Nondiscrimination in Health Programs and Activities*, concerns the prohibition of discrimination on the basis of race, color, national origin, sex, age or disability in certain health care programs and activities. The Final Rule covers any health program or activity, any part of which receives funding from HHS (e.g., hospitals or physicians that accept Medicare or Medicaid funding), any health program that HHS itself administers, and health insurance marketplaces and issuers that participate in those marketplaces. Among other protections, the Final Rule requires that women be treated equally with men in the health care that they receive, that individuals may not be denied care or coverage based on their sex, and that individuals must be treated in a manner consistent with their gender identity, including with respect to access to facilities. In addition to the aforementioned protections, the Final Rule also provides for a number of procedural requirements, including that covered entities with 15 or more employees have a grievance procedure and a compliance coordinator, and that covered entities post notices of nondiscrimination and taglines that translation services are available to those with limited English ability. Section 1557 will be enforced under existing enforcement mechanisms, including requiring covered entities to keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance.

CMS Introduces New Quality Initiative

On May 25, CMS released a request for proposal introducing its latest quality initiative, the formation of Hospital Improvement and Innovation Networks (HIINs). The HIINs, which will be part of the Quality Improvement Initiative, will have a mission to "engage and support the nation's hospitals, patients, and their caregivers in work to implement and spread well-tested, evidence-based best practices." According to CMS, the HIINs will continue the work started by the Hospital Engagement Networks under the Partnership for Patients initiative.

CMS envisions that the HIINs will facilitate the further integration of networks connecting Quality Improvement Organizations and hospitals and "permit the continued and increased systematic use of proven practices to improve patient safety and reduce readmissions, at a national scale in all U.S. hospitals."

CMS has set bold goals for the HIIN initiative, including the achievement of a "20 percent decrease in overall patient harm and a 12 percent reduction in 30-day hospital readmissions as a population-based measure (readmissions per 1,000 people) from the 2014 baseline. . . ." Further details regarding the HIIN initiative are anticipated following selection of HIIN contractors.

Government Expanding Ranks of Health Care Fraud Attorneys

The Department of Health and Human Services Office of Inspector General (OIG) will be increasing the number of attorneys responsible for enforcement of health care fraud and abuse laws according to a statement to Bloomberg BNA by Joanne Chiedi, the OIG's principal inspector general. The hiring initiative will benefit OIG's affirmative litigation team, which focuses on imposition of exclusions and civil monetary penalties under the Medicare and Medicaid programs. The affirmative litigation team, which is credited with recovering $39.9 million in federal dollars since January 2016, was introduced in June 2015 to assist in enforcement actions that may otherwise be passed over by U.S. attorneys due to the relatively low value of payments in dispute.

NEW JERSEY

Challenge by Hospitals to N.J. Charity Care Mandate Rejected; Future Court Date Beckons

A challenge to the state's charity care mandate brought by eight New Jersey hospitals was rejected on jurisdictional grounds by a three-judge panel of the New Jersey Appellate Division in a May 20 opinion described in a recent article in the New Jersey Law Journal (NJLJ). The panel declined to rule on the merits of the case and instead noted issues with the forum in which the case was brought, specifically that since there had not been any findings of fact and since no record had been developed, the appellate division did not have proper jurisdiction for the case. The hospitals appealed to the appellate division after the state Department of Health declined to rule on the challenge, citing its own inability to rule on a constitutional challenge. The panel noted that the trial court would be the proper venue for the hospitals' claims.

The substance of the claim brought by the hospitals is that the requirement by the state that hospitals provide charity care is an unjust taking of property without compensation. The NJLJ noted, "The hospitals claim that the charity care mandate in the New Jersey Cost Reduction Act … is unconstitutional because it amounts to a taking of property without just compensation, even though they are subsidized by annual legislative appropriations. The relevant portion of the statute says 'no hospital shall deny any admission or appropriate service to a patient on the basis of that patient's ability to pay or source of payment.'" The article notes that while the legislature appropriated $675 million for charity care in 2014 and $650 million in 2015, the hospitals bringing the action all noted that, despite the state funding, they would be losing between $980,000 and $16.8 million based on the requirements under the act. While the NJLJ did not state when the hospitals would be bringing suit at the trial court level, the case will merit attention when it eventually comes before a trial court because of the potential impact it will have on the structure of charity care in New Jersey.

New Jersey Bill Tracker

Newborn Insurance Coverage

A2665, a bill extending the time period in which newborns are covered under their parents' health benefits coverage to 60 days after birth, was reported favorably out of the Assembly Financial Institutions and Insurance Committee on June 2. Current law limits the coverage of newborns to 30 days from their birth. At the conclusion of 30 days, the child is without coverage unless the parents enroll the child in a private health benefits coverage policy or in a state or federal program, such as FamilyCare. If enacted, the bill would provide an extended period of time for children to be covered under their parents' health benefits coverage.

Electronic Health Records

A3831, a bill requiring each owner or administrator of an electronic health records system used to transmit electronic prescriptions in New Jersey to ensure that the system meets the federal requirements to accept, process and transmit prescriptions for Schedule II controlled dangerous substances, was reported favorably out of the Assembly Health and Senior Services Committee on June 2. Entities operating or administering a system on the effective date would have one year to meet this requirement as a condition of continuing to transmit electronic prescriptions in this state.

Medicaid Medication Therapy Management Requirement

A1443, a bill requiring the coverage of medication therapy management services in Medicaid and NJ FamilyCare, was reported favorably out of the Assembly Health and Senior Services Committee, with amendments, on June 2. The bill defines medication therapy management as the systematic process performed by a qualified provider that is designed to optimize therapeutic outcomes through improved medication use and reduced risk of adverse drug events, including:

- a medication therapy review and consultation relating to all medications, vitamins and herbal supplements currently being taken by an individual;
- a medication action plan communicated to the individual or the individual's caretaker and the individual's primary health care provider or other appropriate prescriber of medication to address safety issues, inconsistencies, duplicative therapy, omissions and medication costs; and
- documentation and follow-up with the individual or the individual's caretaker to ensure consistent levels of pharmacy services and positive outcomes, including any follow-up discussions with the individual's primary health care provider or other appropriate prescriber as are needed to maintain or improve positive outcomes.

The bill requires the Medicaid and NJ FamilyCare programs to provide coverage for medication therapy management services for enrollees (1) who take one or more prescription drugs for any chronic medical condition, provided the participation standards mirror those for medication therapy management programs under the Medicare Part D program; (2) whose primary health care provider or other appropriate prescriber identifies the individual as having a prescription drug therapy problem and refers the individual to a qualified provider for medication therapy management; or (3) who meet other criteria established by the Commissioner of Human Services.

If enacted, the bill would require that medication therapy review and consultation be conducted at least once per plan or calendar year and be provided in person, unless an in-person review and consultation would present a physical hardship to the enrollee. Only licensed physicians, licensed advanced practice nurses, and registered pharmacies or pharmacists would be permitted to perform medication therapy review and consultation under the bill.

Nursing facilities, assisted-living facilities, assisted-living programs, comprehensive personal care homes, adult day health services facilities and pediatric medical day care facilities would be exempt from the requirement to provide medication therapy management.

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