



# Riker Danzig Health Care Update June 10, 2016

## Publication:

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### **New Jersey State: Selected Proposed Legislation**

- S. 1981 – Introduced – Increases Hearing Aids Assistance for the Aged and Disabled Program annual allowance to \$500.
- S. 2035 – Introduced – Restricts initial prescriptions for opioid drugs to seven day supply.
- S. 2133 – Introduced – Entitles nursing home residents to monitor and record in-room treatment, care, and living conditions using electronic monitoring devices, upon notice to nursing home.
- S. 1980 – Introduced – Requires health insurers to provide coverage for hearing aids.
- A. 3634 – Introduced – Requires one member of board in charge of institution for persons with mental illness or developmental disability to be family member of resident.

### **New Jersey State: Selected Proposed Regulation**

- 48 N.J.R. 565(a) – Proposed – This regulation would impose additional burdens on pharmacies to ensure the integrity of prescription drugs in relation to “temperature excursions.” It is largely in response to perceived regulatory gaps in relation to the treatment of prescription drugs when there have been extended periods of power failure that lead to their exposure to extreme temperatures.

### **Federal: Selected Proposed Legislation**

- S. 2786 – Introduced – Amends Title XVIII of the Social Security Act to provide for payments for certain rural health clinic and federally-qualified health center services furnished to hospice patients under the Medicare program.
- S. 2787 – Introduced – Amends Title XIX of the Social Security Act to provide the same level of federal matching assistance for every state that chooses to expand Medicaid coverage to newly eligible individuals,

regardless of when such expansion takes place.

- H.R. 4819 – Introduced – Directs the Secretary of Health and Human Services (DHHS) to establish a grant program for states that provide flexibility in licensing for health care providers who offer services on a volunteer basis.

## **Federal: Selected Proposed and Adopted Regulations**

- 81 FR 24386-01 – Proposed – The FDA is proposing to ban electrical stimulation devices used to treat aggressive or self-injurious behavior on the grounds that these devices present an unreasonable and substantial risk of illness or injury.
- 81 FR 22525-01 – Adopted – This final rule will reclassify external pacemaker pulse generator (EPPG) devices, which are currently pre-amendments class III devices into class II and to reclassify pacing system analyzers (PSAs) into class II.

## **State Litigation**

- The Appellate Division recently upheld the Division of Banking and Insurance's decision to approve Horizon's tiered OMNIA plan. Eleven hospitals had challenged the decision on the grounds that DOBI had not acted according to the guidelines of the state's insurance laws and Health Care Quality Act. For more information on the decision, see, [Capital Health Regional Medical Center et. al. v. The New Jersey Division of Banking and Insurance](#), case number A-1211-15T3, in the Superior Court of New Jersey, Appellate Division.

## **Federal Litigation**

- Tampa General Hospital recently urged a D.C. Circuit panel to revive their challenge to purportedly low Medicare reimbursements received from the Department of Health and Human Services. In essence, they are arguing that the ACA does not preclude judicial review of HHS's reimbursement methodologies and that the Court should review the methodology. For more information, see, [Florida Health Sciences v. Secretary U.S. DHHS](#), case number 15-5163, in the U.S. Court of Appeals for the D.C. Circuit.
- A New York federal judge ordered the Department of Health and Human Services to review a decision it made to not reimburse a New York-based hospital system upwards of \$15 million. Specifically, the court found that the agency could not justify imposing a reimbursement cap. For more information on why the court rejected the reimbursement cap, see, [New York City Health and Hospitals Corporation et al v. Burwell](#), case number 1:15-cv-00662, in the U.S. District Court for the Southern District of New York.
- The U.S. Supreme Court was recently asked to determine whether the Federal Circuit must use a higher standard of review when determining Vaccine Act cases. The case stems from the parents of a 12-year-old girl, who they argue became a quadriplegic after receiving flu vaccinations as an infant. The appeals court had

said below that the review should be a higher standard than the current standard of “arbitrary and capricious”. For more information on the case, [see, Francia Hirmiz and Peter Hirmiz, as Best Friends of their Daughter, J. H., v. Sylvia Burwell, Secretary of Health and Human Services et al.](#) before the Supreme Court.

- A split Ninth Circuit recently ruled that medical suppliers who fraudulently overbill Medicare can be given longer sentences for that fraud. The reasoning appeared to be that, as Medicare bills submitted by durable medical equipment suppliers are not scrutinized on an individual basis, but instead are occasionally audited, which allows for speedy reimbursements, a supplier who takes advantage of the government breaches the “honor system” involved in the industry. For more information on the cases and the holdings, [see, U.S. v. Adebimpe](#), case number 14-10303, [U.S. v. Sogbein](#), case number 14-10324, and [U.S. v. Abad](#), case number 14-10325, all in the U.S. Court of Appeals for the Ninth Circuit.
- The National Labor Relations Board (NLRB) recently ordered CVS Pharmacy Inc. to amend its current workplace dispute resolution program, which required employees to give up their right to bring collective and class actions, stating that it is an unfair labor practice. For more information on the cases, [see, CVS RX Services Inc. and CVS Pharmacy Inc. and Kenneth Sternfeld](#), case numbers 29–CA–141164 and 29–CA–155028, before the National Labor Relations Board.

## **In the News**

- Centers for Medicare and Medicaid Services (CMS) announced that it would offer the awardees in the Bundled Payments for Care Improvement (BPCI) initiative the opportunity to extend their participation in Models 2, 3, and 4 through September 30, 2018. The goal of these new models is to encourage doctors, hospitals, and other healthcare providers to work together to better coordinate care for patients, both when they are in the hospital and after they are discharged.
- DHHS recently issued new criteria outlining when a person or company will be barred from federal health care programs. The most significant of these updates is that having a compliance program only puts a company in a neutral position, instead of giving “bonus points”. However, not having a compliance program could push a company or individual toward being considered high risk.
- Seven major health insurers in New York announced that they would provide coverage for expensive hepatitis C treatments. These providers are Empire BlueCross BlueShield, United Healthcare/Oxford, Affinity Health Plan, Excellus Health Plan, HealthNow, Independent Health, and MVP Health Plan.
- CMS recently added six new quality measures to its consumer-based Nursing Home Compare website. The significance of these additions is that for the first time, three of the six new quality measures are based on Medicare-claims data submitted by hospitals, which means that this is the first time CMS is including quality measures that are not based solely on data reported by the nursing homes themselves. These three measures relate to the rate of re-hospitalization, emergency room use, and community discharge among

nursing home residents.

- A proposed rule has emerged from an obscure agency called the Railroad Retirement Board, which has the potential to drastically increase the penalties under the False Claims Act. The proposed rule would actually double all of the penalties raising the minimum per claim penalties to \$10,781 from \$5,500 and the maximum per-claim penalties would rise to \$21,563 from \$11,000. It is unclear at this time whether other agencies will follow suit in updating their penalties for FCA violations to account for inflation.

*The list above does not include every proposed or adopted legislation, litigation or guidance document that may impact the health care industry. Instead, it includes only a select few chosen by the authors, and any information in this Update is not intended to provide legal advice. If you are concerned that a proposed or adopted legislation, litigation or guidance document may impact your practice, then you should seek legal advice. Nothing in this Update should be relied upon as legal advice in any particular matter. © 2016 Riker Danzig Scherer Hyland & Perretti LLP.*

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