



Riker Danzig Health Care Update July 15, 2019

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New Jersey State: Selected Proposed and Adopted Legislation

- S. 3312 – Adopted – Requires certain hospitals to provide hospital-based or hospital-linked violence intervention programs to be designated as Level One or Level Two trauma centers. For the complete statute, click [here](#).
- S. 3375 – Adopted – Establishes a maternal health care pilot program to evaluate shared decision-making tool developed by DOH and used by hospitals providing maternity services, and by birthing centers. For the complete statute, click [here](#).
- S. 3651 – Adopted – This bill requires all health insurance carriers that currently sell Medicare supplement insurance to the over-65 population to also offer, at a minimum, Medicare Supplement Plans C and D coverage to the over-50 population who become eligible due to disability on or after January 1, 2020. For the complete statute, click [here](#).
- A. 3717 – Adopted – Prohibits pharmacy benefits managers from making certain retroactive reductions in claims payments to pharmacies and requires pharmacy benefits managers to disclose certain product information to pharmacies. For the complete statute, click [here](#).
- A. 5363 – Adopted – Requires carriers that offer health benefits plans to provide new or existing subscribers with notification of certain hospital and health system contract expirations. For the complete statute, click [here](#).
- A5098 – Vetoed – This proposed statute increased Medicaid rates, over time, from \$16 to \$25 for personal care service for the elderly, sick and disabled living at home. These workers assist with daily tasks such as bathing, dressing, and meal preparation. Despite passing both the Assembly and Senate, the Governor vetoed the bill because of budgetary concerns. For the complete statute, click [here](#).
- S.49 – Proposed – This proposed statute authorizes DOBI to establish a state-based exchange for Medicaid

and certain health insurance plans. For the complete statute, click [here](#).

- S. 984/A. 1590 – Proposed – This proposed bill revises the requirements for hospitals and BME licensed practitioners in providing medical records, including the fees that can be charged. For the complete statute, click [here](#).
- S. 1961 – Proposed – This bill eliminates the requirement that a joint protocol be in place before an advanced practice nurse (APN) may prescribe medications, and sets forth the conditions under which an APN may prescribe medications. For the complete statute, click [here](#).
- S. 2389 – Proposed – The Board of Pharmacy is required to develop a website in order to make prescription drug price information available to New Jersey practitioners. The website must include, among other things, name of the product, whether the drug is brand name or generic, and the per-unit wholesale acquisition cost of the drug. For the complete statute, click [here](#).
- S. 3116 – Proposed – This bill, which has already passed the Senate, requires certain medical facilities to undertake end-of-life planning and training as condition of licensure. For the complete statute, click [here](#).
- S.3809 – Proposed – This proposed bill establishes a rate increase review process in the Department of Banking and Insurance for individual and small employer health benefits plans. A rate increase of 10% or more annually shall be subject to expanded review by the department. In other words, a carrier can avoid review if it increases rates below 10%. For the complete statute, click [here](#).
- S. 3929/A. 5548 – Proposed – This bill requires a pharmacy benefits manager providing services within the Medicaid program to disclose certain information to the Department of Human Services to prevent price spreading. It would require pharmacy benefits managers to disclose information, such as, any pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other benefits. For the complete statute, click [here](#).
- A.382/S. 1612 – Proposed – This bill establishes minimum staffing ratios for direct care staff who provide services to nursing home residents. “Direct care staff” means any registered professional nurse, licensed practical nurse, or certified nurse aide. Under the bill’s provisions, the applicable staffing ratios will be as follows: (1) one direct care staff member for every 6.5 residents on the day shift; (2) one direct care staff member for every 10 residents on the evening shift; and (3) one direct care staff member for every 15 residents on the night shift. For the complete statute, click [here](#).
- A. 3717/S.728 – Proposed – This bill prohibits a pharmacy benefits manager from retroactively reducing payment on a properly filed claim for payment by a pharmacy, otherwise known as direct and indirect remuneration (DIR) fees. For the complete statute, click [here](#).
- A. 5425 – Proposed – Prohibits certain substance use disorder treatment facilities from paying fees, commissions, or rebates to any person to refer patients to facility. For the complete statute, click [here](#).
- A. 5648 – Proposed – Requires certain health care practitioners to disclose criminal and disciplinary history

to patients. For the complete statute, click [here](#)

New Jersey State: Selected Proposed and Adopted Regulations

- 51 N.J.R. 878(a) – Final – This modifies the rules regarding licensed midwives. This rule became effective June 3, 2019. For the complete rule, click [here](#).
- 51 N.J.R. 880(a) – Final – Commencing with the biennial renewal period beginning on September 1, 2017, licensees will be required to take continuing education on prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. This rule became effective June 3, 2019. For the complete rule, click [here](#).
- 51 N.J.R. 1056(a) – Final – This modifies the rule on reimbursing ambulatory surgical centers so that reimbursements under Medicaid and New Jersey Family Care are linked to Centers for Medicare and Medicaid Services (CMS). For the complete rule, click [here](#).
- 51 N.J.R. 912(a), 51 N.J.R. 916(a), 51 N.J.R. 919(a), 51 N.J.R. 926(a), 51 N.J.R. 931(a), 51 N.J.R. 934(a), 51 N.J.R. 946(a) – Proposed – These proposed regulations involve new telemedicine regulations for midwives, athletic trainers, genetic counselors, physical therapists, psychologists, psychoanalysts, and orthotists, pedorthists, and prosthetists. All comments are due by August 16, 2019. For the complete proposals, click the links below:

[51 N.J.R. 912\(a\)](#)

[51 N.J.R. 916\(a\)](#)

[51 N.J.R. 919\(a\)](#)

[51 N.J.R. 926\(a\)](#)

[51 N.J.R. 931\(a\)](#)

[51 N.J.R. 934\(a\)](#)

[51 N.J.R. 946\(a\)](#)

- 51 N.J.R. 923(a) – Proposed – The Board of Nursing proposed these rules concerning an advanced practice nurse dispensing narcotic drugs for maintenance treatment or detoxification treatment if he or she has met the training and registration requirements of 21 U.S.C. § 823. Comments are due by August 16, 2019. For a complete review of the proposal, click [here](#).
- 51 N.J.R. 923(a) – Proposed – The Board of Nursing is proposing a new rule that regulates the transmission of electronic prescriptions by advanced practice nurses to licensed pharmacies. Comments are due by August 16, 2019. For a complete review of the proposal, click [here](#).

Federal: Selected Proposed and Enacted Legislation

- S. 1448 – Proposed – This proposed statute amends the Controlled Substances Act to require warning labels for prescription opioids. For a complete review of the proposal, click [here](#).
- S. 1532 – Proposed – This requires the Government Accountability Office to study the role pharmaceutical benefit managers play in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations, and for other purposes. For a complete review of the proposal, click [here](#).
- S. 1497 – Proposed – This proposed statute, called the “Health Care Price Check Act of 2019” requires the Secretary of DHS to provide a toll free number and website within a certain period of time so that Medicare recipients can determine costs for items and services under parts A and B of Medicare. For a complete review of the proposal, click [here](#).
- S. 1607 – Proposed – This provides a patient at the time of scheduling the opportunity to inform the hospital that they would like in-network treatment only for the procedure, and if such in-network treatment is not available at the time of treatment, then the hospital must pay the difference. For a complete review of the proposal, click [here](#).
- H.R. 2803 – Proposed – This proposed statute requires health insurance coverage for the treatment of infertility. There is a companion bill in the Senate, S. 1461. For a complete review of the proposal, click [here](#).
- H.R. 2917 – Proposed – This proposed statute is intended to hold pharmaceutical companies accountable for dubious marketing and distribution of opioid products and for their role in creating and exacerbating the opioid epidemic in the United States. For the complete bill, click [here](#).
- H.R. 2990 – Proposed – This proposed statute permits states to designate without any mileage limitations facilities that are located in rural areas as critical access hospitals, and for other purposes. For the complete statute, click [here](#).
- H.R. 3105 – Proposed – Requires the Secretary of Health and Human Services to assess an annual fee against opioid manufacturers. For a complete review of the proposal, click [here](#).
- H.R. 3379 – Proposed – To amend the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 5 years. For the complete statute, click [here](#).
- H.R. 3386 – Proposed – To amend Title XI of the Social Security Act to require hospitals and critical access hospitals to provide uninsured individuals with access to the lowest negotiated rate for items and services furnished to such individuals. For the complete bill, click [here](#).
- H.R. 3406 – Proposed – To amend Title XVIII of the Social Security Act to improve measurements under the skilled nursing facility value-based purchasing program under the Medicare program, and for other purposes. For the complete statute, click [here](#).
- H.R. 3408 – Proposed – To amend Title XVIII of the Social Security Act to require prescription drug plan sponsors to include real-time benefit information as part of such sponsor’s electronic prescription program

under the Medicare program so that beneficiaries can get immediate pricing information. For the complete statute, click [here](#).

Federal: Selected Proposed and Adopted Regulations

- 84 FR 24610 – Final – This final rule updates the requirements for the Programs of All-Inclusive Care for the Elderly, otherwise known as PACE. The changes are designed to afford more flexibility to PACE Organizations and state administering agencies to encourage the expansion of the PACE program, thus, increasing access for participants. As an example, the proposed rule allows non-physician medical providers practicing within the scope of their state licensure to serve in place of primary care physicians in some capacities. The final rule becomes effective 8/2/19. For the final rule, click [here](#).
- 84 FR 27069 – Final – This final rule concerns an extension of the timeline for publication of the “Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care” final rule. This rule updates the requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs. It was supposed to be finalized by June 14, 2019 but has been extended to June 16, 2020. For the final rule, click [here](#).
- 84 FR 28888 – Final – This final rule changes the rules regarding health reimbursement arrangements (HRAs) and other account-based group health plans to provide more access to affordable healthcare. The final rules allow integrating HRAs with individual health insurance coverage or Medicare, if certain conditions are satisfied. It also sets forth conditions under which certain HRAs will be recognized as limited excepted benefits. For the file rule, click [here](#).
- 84 FR 28450 – Proposed – Under this proposal, Part D plan sponsors would be required to support version 2017071 of the National Council for Prescription Drug Programs SCRIPT standard for four electronic Prior Authorization (ePA) transactions, and prescribers would be required to use that standard when performing ePA transactions for Part D-covered drugs they wish to prescribe to Part D-eligible individuals. The proposed ePA transaction standard would provide for the electronic transmission of information between the prescriber and Part D plan sponsor. If the prescriber enters such a prescription into an eRx system, a message will be returned to the provider indicating that a prior authorization is required. Use of the ePA transactions would then enable the prescriber to submit the information required to fulfill the terms of the PA in real time. Comments are due August 16, 2019. For the file rule, click [here](#).
- 84 FR 27070-01 – RFI – This RFI seeks feedback from the medical community to learn how CMS administrative requirements and processes affect their daily work and ability to innovate in care delivery. This RFI solicits additional public comment on ideas for regulatory, subregulatory, policy, practice, and procedural changes that reduce unnecessary administrative burdens for clinicians, providers, patients and their families. Comments are due August 12, 2019. For the complete proposed rule, click [here](#).

- 84 FR 30968-01 – Proposed Rule – This proposed rule concerns the FDA's proposed amendments to regulations on the use of master files for biological products. This action, if finalized, will allow certain biological products approved under the FDA to continue to incorporate by reference information about drug substances, drug substance intermediates, or drug products contained in master files after those products are deemed to be licensed under the Public Health Service Act (PHS Act) on March 23, 2020. The proposed rule also codifies FDA's practice of permitting applications for biological products submitted under the PHS Act to incorporate by reference information other than drug substance, drug substance intermediate, or drug product information contained in a master file. Comments are due August 27, 2019. For the complete proposed rule, click [here](#).
- By executive order, the Trump Administration has distinguished between the charges that providers bill and the rates negotiated between payers and providers, and believes that by disclosing those rates, patients will have more information to shop for services. As a result, within 60 days of the date of the order, the order requires the Secretary of Health and Human Services to propose a regulation, consistent with applicable law, to require hospitals to publicly post standard charge information, including charges and information based on negotiated rates and for common or shoppable items and services. The regulation will also require the posting of standard charge information for services, supplies, or fees billed by the hospital or provided by employees. For the complete executive order, please click [here](#).

Issued Guidance

- The U.S. Department of Justice Criminal Division announced the release of an updated guidance on evaluating corporate compliance programs entitled *Evaluation of Corporate Compliance Programs*. The first guidance was issued in 2017. The Guidance sets forth six components prosecutors may consider in determining whether to file criminal charges, and in negotiating plea and other agreements. For a complete review of the guidance, click [here](#).
- CMS issued draft guidance for the new hospital co-location rules, which broadens the use of shared space between hospitals and hospitals and other health care entities. For a complete review of the draft guidance, click [here](#).

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. We send these Updates to our clients and friends to share our insights on new developments in the law. Nothing in this Update should be relied upon as legal advice in any particular matter. © 2019 Riker Danzig Scherer Hyland & Perretti LLP.

If you have any questions about the issues discussed in this Update, please contact [Khaled J. Klele](#) or [Latoya Caprice Dawkins](#).

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