New Jersey Legislative Update - January 2021

1/31/2021

Bill Introduced to Require Pharmacy Audit Procedures - On December 21, 2020, Bill S3304 was introduced in the New Jersey Senate to establish procedures by which entities are required to conduct audits of pharmacies. The Bill would establish the "New Jersey Pharmacy Audit Bill of Rights" and would include certain procedures and processes which entities auditing a pharmacy must follow. The Bill defines "entity" as a hospital service corporation; medical service corporation; managed care company; insurance company; third-party payor; pharmacy benefits manager; any entity licensed by the Department of Banking and Insurance; or any entity that represents such companies, groups, or departments. Audits would be required to be conducted in accordance with certain requirements concerning the scope of an audit, procedures to properly perform an audit, recordkeeping, and recoupment. Additionally, the entity conducting an audit would not be permitted to use the accounting practice of extrapolation in calculating recoupments or penalties for audits. Recoupments of any disputed funds would only be permitted to occur after the final internal disposition of an audit, including the appeals process as set forth in the Bill.

Board of Medical Examiners Proposes Amendments to Rules to Repeal Outdated Restrictions on Reproductive Care

- On January 4, 2021, the New Jersey State Board of Medical Examiners (BME) released proposed amendments to the BME rules to expand access to reproductive healthcare and to repeal outdated rules that place medically unwarranted restrictions on abortion in New Jersey. The BME is proposing these amendments based upon its findings that the current restrictions are medically unnecessary, do not protect

patients' health or safety, and restrict access to abortion care in New Jersey. Written comments to the proposed amendments must be submitted to the BME by March 5, 2021.

Current BME rules provide that after 14 weeks of gestation, abortions are restricted to Department of Health (DOH)- licensed ambulatory care facilities (ASCs) or hospitals, depending on the methods used to perform the procedure and the gestational age. The current rules also only permit licensed physicians to perform abortion procedures in New Jersey (the "physician-only" rule), with the exception of medication-based abortion, which is not considered a procedure subject to the physician-only rule.

Key aspects of the proposed amendments include the following:

- Repeal the requirement that all abortions be performed only by a physician (i.e., repeal of the physician-only rule);
- Repeal the rule barring office-based terminations beyond 14 weeks of gestation;
- Permit advanced practice nurses, physician assistants, certified nurse midwives, and certified midwives to perform early
 aspiration terminations of pregnancy (in addition to medication-based termination of pregnancy, which is already
 permitted); and
- Update the regulations to integrate reproductive care within the generally applicable BME rules which ensure the safety of patients who undergo surgery or special procedures in an office setting.

State Board of Medical Examiners Revises Opioid Regulations – On January 19, 2021, the New Jersey State Board of Medical Examiners revised its regulations which govern the prescription of opioids to address the ongoing opioid epidemic and to further increase the public availability of naloxone. The revised regulations provide that when controlled dangerous substances are continuously prescribed for management of chronic pain, the practitioner must provide a prescription for an opioid antidote if the patient has one or more prescriptions totaling 90 morphine milligram equivalents or more per day, or is concurrently obtaining an opioid and a benzodiazepine. The practitioner must also document within the patient record the action taken. The Board believes that mandating the co-prescribing of an opioid antidote under these circumstances will help reduce the risk of

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overdose deaths.

The revised regulations apply to physicians, podiatrists, physician assistants, and certified nurse midwives. In addition, in order to be consistent with New Jersey law (specifically P.L. 2017, c.341 which was approved on January 16, 2018), the definition of "chronic pain" was revised to mean pain that persists or recurs for more than three months. Furthermore, in accordance with the revised definition of "chronic pain," the obligation of a practitioner to enter into a pain management agreement was revised so that it will not commence until the third month of treatment, regardless of the number of prescriptions that may have been issued over the three-month period. Also, on January 19, 2021, the New Jersey State Board of Dentistry, the New Jersey Board of Nursing, and the New Jersey State Board of Optometrists introduced proposed revisions to their respective regulations governing the prescription of opioids which are identical to the revisions adopted by the Board of Medical Examiners.