I. NEW JERSEY DEVELOPMENTS

A. New CME Requirement Regarding End of Life Care

On December 20, 2011, N.J.S.A. 45:9-7.7 was passed into law, which implemented a new continuing medical education (“CME”) requirement regarding end-of-life care. The new law became effective as of January 1, 2013. The new law requires that the number of credits of CME for all physicians licensed in New Jersey include two credits of educational programs related to end-of-life care.

The New Jersey State Board of Medical Examiners (“BME”) may waive the requirement for a specific individual if the BME deems it appropriate to do so in accordance with N.J.S.A. 45:9-7.1. Under N.J.S.A. 45:9-7.1, the BME may waive requirements for CME on an individual basis for reasons of hardship such as illness or disability, retirement of license, or other good cause.

The BME has indicated that if a licensee believes that the mandate has little applicability to his or her practice area, waivers or extensions can be requested. The licensee must send to the BME, within sixty days of the expiration of the biennial renewal period (i.e., April 30, 2015), by certified mail, return receipt requested, or other proof of delivery, a letter explaining why such waiver or exemption is applicable. However, according to the statute and guidance from the BME, the waiver is only valid for the current biennial period at the time of issuance.

B. New Prescription Blanks Must Be Used After September 20, 2014

The New Jersey Division of Consumer Affairs (“DCA”) has adopted new regulations regarding prescription blanks used by medical practitioners in the State of New Jersey. For prescriptions written after September 20, 2014, practitioners may no longer use the old type of New Jersey Prescription Blanks (“NJPBs”). The new NJPBs may be ordered from any of the approved NJPB vendors and sales representatives from the list on the DCA’s website at http://www.njconsumeraffairs.gov/njpbm.pdf. The new NJPBs are required to contain the following security features:
• Thermochromic ink, which changes color in response to body heat. The heat-activated ink will appear in a small Rx logo on the front of the prescription blank. It will fade when touched, and return to its original color when it cools.

• Microprint of 0.5-point type or smaller. The front of each prescription blank will include a line of microprint that is readable when viewed at 500 percent magnification, but becomes illegible when scanned or photocopied.

• A hollow “VOID” hidden word feature that is invisible on a genuine prescription blank, but should appear in illegally scanned or copied versions.

• A unique 15-digit identification number for each prescription blank. The alphanumeric code will identify the vendor that created the blank, the vendor’s order number, and a six-digit serial number for each separate prescription blank.

• A barcode matching the prescription blank’s unique 15-digit identification number. The barcode will enable pharmacists to scan prescription data into the New Jersey Prescription Monitoring Program (“NJPMP”). The NJPMP, maintained by the DCA, records all prescription sales in New Jersey of Controlled Dangerous Substances and Human Growth Hormone.

• A complete list of all security features will be printed on the back of the prescription blank.

• The new prescription blanks will be green on the front and blue on the back. This will enable them to be more easily distinguished from the old blanks, which are blue on the front and green on the back.

The old prescription blanks must be destroyed with a witness present, who may not be the same individual who destroys the prescription blanks. The prescription blanks may be destroyed by shredding, burning, pulping or pulverization. The witness must complete the Certification of the Destruction of New Jersey Prescription Blanks Form (NJPB Form II-A), which must then be sent by mail to the New Jersey Office of the Attorney General, Division of Consumer Affairs, Drug Control Unit – NJPB, 124 Halsey Street, 6th Floor, P.O. Box 45045, Newark, New Jersey 07101 or via email to NJPB@dca.lps.state.nj.us. Additional requirements regarding the destruction of prescription blanks are included on the form.

C. Bill Introduced Revising Language in Mammography Reports

On August 4, 2014, A3560, a bill revising the language in mammography reports concerning the detection of extremely dense breast tissue, was introduced into the New Jersey State Assembly. The bill was referred to the Assembly Health and Senior Services Committee.

As of May 1, 2014, New Jersey law provides that whenever a patient undergoes a mammogram, the patient’s mammography report must include language that indicates that the patient may have dense breast tissue, which may make it more difficult to detect breast cancer. The bill, if passed into law, would only require the notice be provided to patients whose mammogram
demonstrates extremely dense breast tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology. The notice in the patient’s report would include language expressly indicating that extremely dense breast tissue was detected.

Specifically, as presently written, the bill revises the language as follows (bracketed language is language that will be deleted from the present notice language and underlined language indicates the new language):

Your mammogram [may show that you have dense breast tissue as determined by the Breast Imaging Reporting and Data System established by the American College of Radiology] shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, in some cases, dense breast tissue can make it harder to find cancer on a mammogram and may also be associated with a risk factor for breast cancer. Discuss this and other risks for breast cancer that pertain to your personal medical history with your health care provider. At that time, ask your health care provider if more screening tests might be useful, based upon your risk. A report of your results was sent to your health care provider. You may also find more information about breast density at the website of the American College of Radiology, www.acr.org.

D. Court Reinstates Defamation Suit against Insurance Company by Medical Provider

If a recent U.S. District Court of New Jersey decision is any indication, then health care facilities and insurers should be mindful of what they publish regarding medical providers. In a recent New Jersey case, the court reinstated a defamation suit by an ambulatory surgical center and hospital and their owner (“Medical Provider”) against Connecticut General Life Insurance Company and its spokesman (“Company”). The Medical Provider alleged that the Company committed defamation when the spokesman accused the Medical Provider of fraud in a published newspaper article.

The article contained the following language, at issue in the case:

There are a number of facilities and doctors in New Jersey that pursue an out-of-network business model. That strategy is responsible for driving up claim costs, with significantly higher charges than those billed by in-network doctors and facilities. The waiver of cost-sharing as a routine business practice is deceptive and fraudulent. Providers who engage in this are driving higher costs for all New Jersey consumers.

Although the case was originally dismissed because the Medical Provider did not show that the Company made the statement with actual malice, the court reinstated the action after the Medical Provider amended its complaint to include information regarding its agreement with a contractor who would negotiate claims submitted to the Company at 60% to 70% of the “usual, customary and reasonable rates which non-participating providers are entitled to under existing law.”

E. DOBI Adopts New Regulations on Independent Health Care Appeals Program

The New Jersey Department of Banking and Insurance (“DOBI”) has adopted regulations that would implement a state requirement that health care providers prominently display a notice concerning the state’s Independent Health Care Appeals Program (“IHCAP”). The IHCAP is an external review program administered by DOBI that reviews adverse utilization management
determinations made by carriers with respect to any health benefits plan for which the carrier uses utilization management features. Both the covered individual and the provider, acting on the covered individual’s behalf and with the individual’s consent, can use this program.

The new regulations apply to general hospitals and physicians and prescribe the size, content and format of the notice that must be displayed. The regulations became effective May 5, 2014 but providers were not required to be in full compliance until August 3, 2014 in order to give providers time to produce and post the required notices.

II. FEDERAL DEVELOPMENTS

A. CMS Proposes Updates to Physician Fee Schedule Policies

On July 11, 2014, the Centers for Medicare & Medicaid Services (“CMS”) published its proposed updates to the Medicare Physician Fee Schedule (“PFS”) and Part B payment policies that will affect services provided by physicians on or after January 1, 2015 (CMS-1612-P).

Key features of the proposed rule include the following:

- Payment impact on obstetrics/gynecology should be 0% assuming that the sustainable growth rate formula cut of 20.9% due to go into effect on April 1, 2015 is repealed or postponed.
- Adjusting payments under the PFS to more accurately reflect local differences in the cost of operating a medical practice.
- New malpractice RVUs for all services.
- Collection of data on services furnished in off-campus provider-based departments beginning in 2015.
- Changes to the Open Payments Program, regarding the disclosure of relationships between providers and pharmaceutical and device companies, including removal of an exclusion for reimbursement related to CME; requiring the reporting of the marketed name of the related covered and non-covered drugs, devices, biologicals or medical supplies unless the payment is not related to the product; and requiring manufacturers to report stocks, options and other ownership interests as separate categories.

B. AMA Encourages Hospitals to Adopt More Rigorous Conflict of Interest Policies

At its annual meeting in Chicago during the week of June 9, the American Medical Association (“AMA”) House of Delegates adopted a resolution encouraging hospitals to adopt more rigorous conflict of interest policies. The AMA recommends that hospital policies governing interactions of hospital personnel, including physicians and other staff, with pharmaceutical, medical device and other industry representatives, be developed through a collaborative effort among a hospital’s organized medical staff, administration and governing body. Furthermore, hospital conflict of interest policies should be consistent with applicable AMA policies and ethical opinions regarding medicine-industry interaction. As part of the resolution, the AMA will inform the American Hospital Association of the
AMA’s position in the hopes of spurring hospitals to adopt more rigorous and consistent conflict of interest policies.

C. **CMS Implements Fingerprint-Based Background Checks for High Risk Providers**

As part of the enhanced enrollment screening provisions contained in the Affordable Care Act, the Centers for Medicare & Medicaid Services is implementing fingerprint-based background checks for newly and currently enrolled Medicare providers and suppliers with ownership interest in “high-risk” service categories. High-risk provider categories include suppliers of durable medical equipment, prosthetics, orthotics and supplies, and home health agencies.

Once fully implemented, the fingerprint-based background check will be completed on all individuals with a 5% or greater ownership interest in a provider or supplier that falls under the high-risk category. Fingerprinting will be phased in, with notification coming from the Medicare Administrative Contractors. Relevant individuals will have 30 days from notification to be fingerprinted, and are responsible for the associated costs.

D. **Online Tool Introduced to View Physician Medicare Reimbursements**

The Centers for Medicare & Medicaid Services (“CMS”) has introduced an online look-up tool that the public can use to access recently released data on services and procedures provided to Medicare beneficiaries by physicians and other health care professionals. The introduction of the look-up tool coincides with CMS’s release of Medicare data on payments and submissions from 2012. On April 11, 2014, CMS publicly released data on services and procedures provided to Medicare beneficiaries by physicians and other health care professionals. The data set contains information on over 880,000 distinct health care providers, collectively representing $77 Billion in Medicare Part B Fee-For-Service payments in 2012, and includes payments and submitted charges for approximately 6000 different types of services and procedures, listed by provider.

The tool allows users to look up a provider by National Provider Identifier or by name and location. The tool will then return detailed information about that provider, including services and procedures provided to Medicare beneficiaries, utilization information, payment amounts (allowed amount and Medicare payment) and submitted charges organized by the Healthcare Common Procedure Coding System.

The CMS look-up tool can be accessed through the following link: https://data.cms.gov/use-agreement/data-limitations/provider-explorer. However, CMS is careful to point out the limitations of the accessible data. For example, the tool only provides data on care delivered to Medicare beneficiaries in the fee-for-service program and thus may not represent a provider’s entire practice. There is no information on quality of care and there is nothing to account for differences in the sickness of patients treated by different providers. Furthermore, the tool does not discern whether procedures were performed in an office or a facility setting, which affects the reimbursement rate. Despite these limitations, CMS believes the look-up tool advances its goal of providing the public with transparency into the medical services physicians provide and how much they are reimbursed for these services.