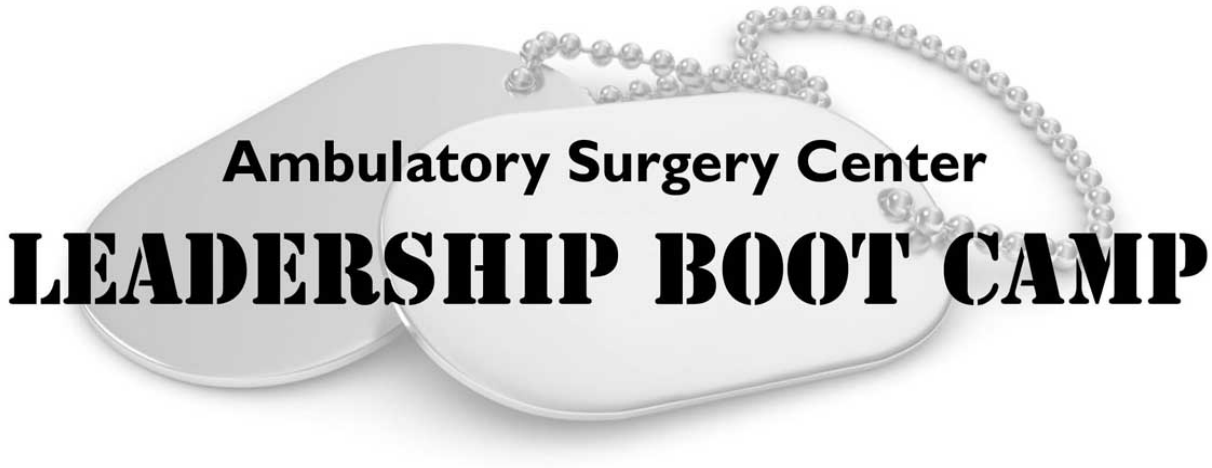

Regulatory and Litigation Update

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The Out-of-Network Consumer Protection, Transparency, Cost Containment, and Accountability Act

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Disclosures In General

Despite its name, the Transparency Act imposes obligations on in-network providers. All facilities, whether in-network or out-of-network must provide the following:

- Before scheduling an appointment, you must disclose to the patient whether your center is in-network or out-of-network with the patient's insurance.
- Advise the patient to check with the physician arranging the facility services to determine whether or not that physician is in-network or out-of-network with the patient's insurance.
- Provide information about how to determine the insurance plans participated in by any physician who is reasonably anticipated to provide services to the patient.

N.J.S.A. 26:2SS-4(a)(1-2).

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In-Network Disclosures

If your center is in-network with the patient's insurance, you must disclose the following:

- The patient's financial responsibility as to the facility will be limited to the patient's copayment, deductible, or coinsurance.
- Unless the patient has knowingly selected an out-of-network provider to provide services, the patient will not incur any out-of-pocket costs in excess of the charges applicable to an in-network procedure.

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In-Network Disclosures

- Any attempt by the facility to collect money in excess of the patient's copayment, deductible, or coinsurance should be reported to the patient's insurance carrier and the relevant regulatory entity.
- Unless the covered person has knowingly selected an out-of-network provider to provide services, any attempts by an in-network provider to collect money in excess of the patient's copayment, deductible, or coinsurance should be reported to the patient's insurance carrier and the relevant regulatory entity.

N.J.S.A. 26:2SS-4(a)(3)(a)-(c).

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Self-Funded Plans

- Certain health care services may be provided on an out-of-network basis.
- The patient may have a financial responsibility applicable to services provided by an out-of-network provider in excess of the patient's copayment, deductible, or coinsurance, and the patient may be responsible for any costs in excess of those allowed by the person's self-funded plan.
- The patient should contact the covered person's self-funded health benefits plan sponsor for further consultation on those costs.

N.J.S.A. 26:2SS-4(3)(d).

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Public Disclosures

The facility must create a list of its standard charges for items and services provided by the facility, and make it available to the public. N.J.S.A 26:2SS-4(b).

The facility must modify its website to include the following information:

- A statement that: (1) physician services provided in the facility are not included in the facility's charges; (2) physicians who provide services in the facility may or may not participate with the same insurance plans as the facility; (3) the patient should check with the physician arranging for the facility services to determine the insurance plans in which the physician participates; and (4) the patient should contact their carrier for further consultation on those costs.

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Public Disclosures

- The insurance plans in which the facility is a participating provider.
- The name, mailing address, and telephone number of any hospital-based physician groups that the facility has contracted with to provide services including, but not limited to, anesthesiology, pathology, and radiology.
- The name, mailing address, and telephone number of any physicians employed by the facility and whose services may be provided at the facility, and the insurance plans in which they participate.

N.J.S.A 26:2SS-4(c)(1)-(4).

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SELF-PAY

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- N.J.A.C. 13:35-6.11(b) states: "A licensee of the Board of Medical Examiners shall not charge an excessive fee for services. A fee is excessive when, after a review of the facts, a licensee of ordinary prudence would be left with a definite and firm conviction that the fee is so high as to be manifestly unconscionable or overreaching under the circumstances."
- Leslie v. Quest Diagnostics, Inc., Civ. A. No. 17-1590 (Oct. 2019). This was a class action filed by self-pay patients against Quest.
- Can you charge self-pay patients less than the prices that you publicize?

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Telemedicine

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- State statutes, including New Jersey, require the physician to be licensed in the state that the patient is located. N.J.S.A. 45:1-62(b).
- The provider is not only subject to the law of the State where the patient is located, but you are also subject to New Jersey law. N.J.S.A. 45:1-62(b).
- The provider must disclose certain information to the patient, including their professional credentials.
- Beware of Telemedicine companies who want you to prescribe medications and/or durable medical equipment for patients who live outside of the state of your practice.

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- For an initial encounter, the provider must review the patient's entire medical history and medical records. N.J.S.A. 45:1-62(c)(4).
- Unless the provider has established a proper provider-patient relationship with the patient, you cannot issue a prescription to a patient based solely on the responses provided in an online questionnaire. N.J.S.A. 45:1-62(d)(2).
- A provider cannot issue a prescription for a Schedule II controlled substance until after an initial in-person examination of the patient, and then you must have in-person visits every three months for the duration of the time the patient is being prescribed the Schedule II controlled substance. N.J.S.A. 45:1-62(e).

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Recently Adopted New Jersey Statutes and Regulations

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- S3334: This statute exempts surgical technologists employed at licensed one room surgery centers from meeting certification requirements. This bill became law in August 2019.

- A1094: Bans employers from asking prospective employees information about salary history. This went into effect in January 2020.

- S3036: This bill prohibits a provider from reporting unpaid charges under the Workers' Compensation Law. This went into effect in January 2020.

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Recent Federal Regulations

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Reduction In Legal Fentanyl

- In September 2019, the DEA proposed to reduce the amount of fentanyl produced by 31 percent, hydrocodone by 19 percent, hydromorphone by 25 percent, oxycodone by nine percent and oxymorphone by 55 percent.
- The DEA finalized the reductions effective for 2020.

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84 FR 61142

Ambulatory Surgery Center Prospective Payment System for Calendar Year 2020: (Final Rule)

- CMS decided to continue to apply the hospital market basket update to ASC payment rates through 2023. Based on the basket, payment rates went up, on average, by 2.6%.
- CMS added eight codes to the ASC-payable list, including total knee arthroplasty (TKA) and six coronary intervention procedures.

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- This rule added the ASC-19 measure to the ASCQR Program for 2024, which is a risk-adjusted outcome measure of acute, unplanned hospital visits within 7 days of a general surgery procedure performed at an ASC among Medicare FFS patients aged 65 years and older.

- CMS finalized the removal of total hip arthroplasty (THA) and six spine codes from the inpatient-only (IPO) list for 2020 and, therefore, these procedures may now be performed in the hospital outpatient setting. TKA and many other procedures that now could be performed in ASCs were initially removed from the IPO list before eventually being added to the ASC-payable list.

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84 FR 51732

- The purpose of this rule is to remove "unnecessary, obsolete or excessively burdensome Medicare compliance requirements for healthcare providers and suppliers." This rule became effective in November 2019. (Final Rule)

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How Does 84 FR 51732 Impact ASCs?

- Transfer Agreements with Hospitals: ASCs will no longer be required to have a written transfer agreement or hospital admitting privileges for all physicians who practice in the ASC. Instead, ASCs will be required to periodically provide the local hospital with written notice of their operation and patient population served.

- Emergency Preparedness: ASCs are now required to review their Emergency Plan (EP) every two years instead of annually. ASCs are only required to conduct just one testing exercise per year, instead of two.

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- Requirements for Medical History and Physical Assessment: CMS eliminated the requirement that each patient have a medical history and physical assessment completed by a physician not more than 30 days before the scheduled surgery. Instead, ASCs have to develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. CMS did provide some rules as to what should be in the policy.

- If New Jersey law or accrediting body requirements are more restrictive than the new CMS Conditions for Coverage, those other requirements take precedence.

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Imaging Services

- Starting January 1, 2020, CMS implemented new appropriate-use criteria ("AUC") for advanced diagnostic imaging services provided in ASCs, physician offices and other settings.
- The AUC will require professionals to consult a clinical decision support mechanism (CDSM) before ordering Medicare Part B advanced diagnostic imaging services. A CDSM is an electronic tool that will tell ordering clinicians whether their order adheres to AUC.
- Claims will not be denied during the 2020 testing period but denials may start January 1, 2021.

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85 FR 7666

This proposal continues prior authorization requirements for 45 Healthcare Common Procedure Coding System (HCPCS) codes on the Required Prior Authorization List of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Items. It also adds six more codes to this list. The Rule becomes effective on May 20, 2020.

(Proposed Regulation)

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The six additional codes are:

- L5856: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type.
- L5857: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type.
- L5858: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type.
- L5973: Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source.
- L5980: All lower extremity prostheses, flex foot system.
- L5987: All lower extremity prosthesis, shank foot system with vertical loading pylon.

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Federal Litigation

United States v. AseraCare: The Eleventh Circuit raised the bar in proving a claim under the False Claims Act. The Court ruled that a mere difference of clinical opinion among physicians is not enough to prove "falsity" under the False Claims Act.

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MedPac

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- In January 2020, MedPac issued its payment recommendations.
- In terms of ambulatory surgery centers, MedPac recommended, as it has done in the past, that ASCs report cost data.
- MedPac is also recommending creating an ASC value based purchasing (VBP) program so that ASCs are not just reporting data under the ASCQR Program but are being rewarding through additional payments for improving quality.

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Proposed New Jersey Statutes

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Since January 1, 2020, there have been over 250 statutes proposed that impact healthcare:

- Expanding services and/or regulatory requirements on physicians and facilities
- Medicaid
- Pharmacy
- Insurance

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A547: "Health Care Consumer's Out-of-Network Protection, Transparency, Cost Containment, and Accountability Act"

- It adds requirements on out-of-network physicians and facilities.
- The out-of-network physician and/or facility must provide an estimate of costs to the patient who elects to receive out-of-network services and the out-of-network provider must obtain the patient's "written assent" that the patient will pay.
- Additional notice requirements imposed on employers who operate self-funded plans to inform employee which physicians and facilities are in-network.

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Establishes a Physician's Medical Bill Dispute Resolution Review Program in the State Board of Medical Examiners to resolve disputes between out-of-network physicians and payors.

- Consist of 21 physicians in active medical practice to be appointed by the Governor in consultation with the Medical Society of New Jersey.

- Each dispute will be resolved by a Panel of 3 physicians within the same specialty.

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The Panel will consider ten factors in determining the owed amount, including:

1) Whether there is a gross disparity between the fee charged by the physician as compared to the fees paid to the physician for the same services rendered to other patients in plans in which the physician is participating;

2) Fees paid by the plan to reimburse similarly qualified physicians for the same services in the same region who are not participating with the health benefits plan;

3) The physician's usual charge for comparable services with regard to patients in plans in which the provider is not participating;

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4) The average reimbursement accepted by the physician from that carrier or third party administrator in the past 12 months;

5) The Medicare rate paid in the same region to the same type of physician for the same classification of health care facility in which the service took place; and

6) The billed amount for the same type of procedure as reported by a recognized health claims data base for all geographic areas of the State.

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- The database to be used shall not have an ownership or controlling interest in, or be an affiliate of any entity with a pecuniary interest in the application of the database, including an insurer, physician group, holding company of an insurer, or health insurance trade association.

- The Panel shall also have, if warranted, the authority to review the patient's treatment to determine whether or not the treatment provided was medically necessary.

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The proposed bill also establishes a Health Care Facilities Medical Bill Dispute Resolution Program to resolve disputes between out-of-network facilities and payors.

- Consist of 11 individuals representing health care facilities appointed by the Governor in association with the New Jersey Hospital Association.
- Each dispute will be resolved by a Panel of 3 individuals.

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- The Panel will consider several factors in determining the owed amount: (1) Whether there is a significant disparity between the fees charged by the facility as compared to fees paid to participating facilities for the same service *or* fees charged by the facility to health benefits plans in which it is a participating provider; and (2) The facility's actual cost in providing the services, as demonstrated by the facility, and whether that cost is consonant with the actual services rendered and the demographics of the population served by that facility.

- The Panel may also consider whether a service or services were deemed to be medically necessary.

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A685: Prohibits requiring licensed physician from obtaining Board Certificate as a condition of licensure, reimbursement, employment, or admitting privileges at a hospital in the State.

A796: Requires licensure of pain management clinics.

S1087: This statute extends the date for one room centers to apply for licensure from one year after the statute is adopted. The previous statute, S278, became law in January 2018 and required one room centers to apply for licensure by January 2019.

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S933: Allows ASCs to deduct Medicaid payments when calculating the gross receipt assessment under N.J.S.A. 26:2H-18.57(7)(b).

S934: Allows ASCs to deduct up to $125,000 of Medicare payments in calculating the gross receipt assessment under N.J.S.A. 26:2H-18.57(b).

A1686: This bill reduces the assessment rate under 26:2H-18.57(7)(b) from 2.95% to 2.28% and reduces the cap from $350,000 to $300,000.

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A2439: This statute imposes mandatory patient to registered nurse ratios in facilities including surgery centers.

S1328: New requirements for constructions new health care facilities.

A540: This bill provides all residents of New Jersey with Medicare health care coverage.

S1108: Prohibits anti-tiering clauses in contracts between a provider and a payor.

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A1972: Ensuring Transparency in Prior Authorization Act.

S363: If a payor pre-authorizes a service, then the payor cannot deny payment.

S784: Eliminates pre-authorization for physical and occupational therapy services, prescription drugs and biologics, radiological examinations, durable medical equipment, and surgical services that address a single organ or organ system.

S786: This bill prohibits requiring pre-approval or precertification of medical tests, procedures or prescription drugs covered under a health benefits or prescription drug benefits plan.

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A2652: This bill requires hospital and health care professionals to have separate forms for informed consent and assignment of benefits or financial arrangement forms.

A2672: Limits co-payments and deductibles.

S1511: Limits cancellation fees.

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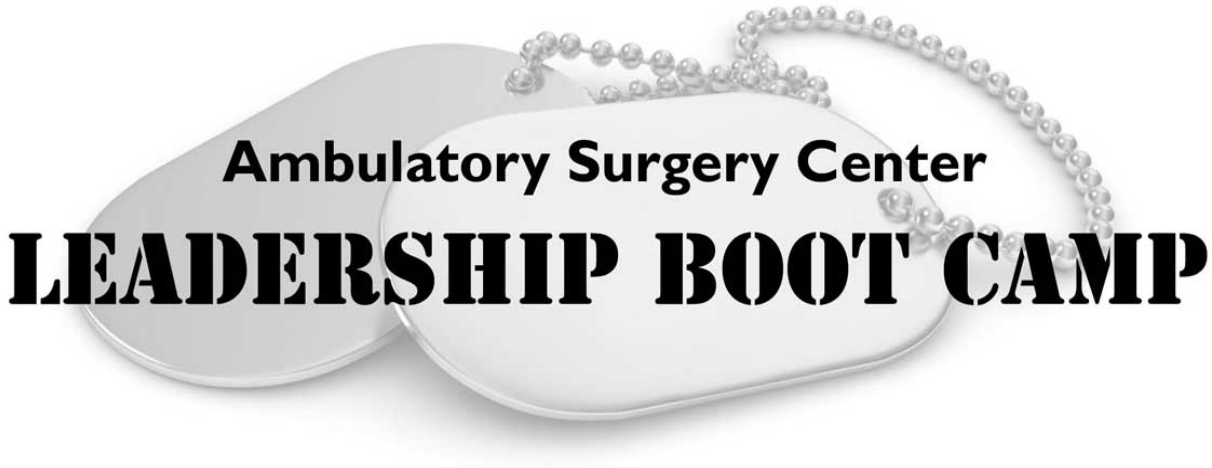

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