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Health Law UPDATE

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FEDERAL UPDATE

CMS Rolls Out New Bundled Payment Program for 2018

The Centers for Medicare & Medicaid Services (CMS) has launched a new program, Bundled Payments for Care Improvement Advanced (BPCI Advanced), to better support health care providers who invest in practice innovation, care redesign, and enhanced care coordination. Under this new voluntary payment model, if expenses for a beneficiary's care fall under a spending target, participants can earn additional payments. In addition to tracking spending, CMS will review the quality of care provided to a beneficiary in deciding whether additional payments will be allocated to its participants. BPCI Advanced will qualify as an Advanced Alternative Payment Model under the Quality Payment Program.

BPCI Advanced participants can receive these additional payments by their performance of 29 inpatient clinical episodes and three outpatient clinical episodes, such as major joint replacements, gastrointestinal obstruction, respiratory infections, and stroke. There are two different types of BPCI Advanced participants. A participant that brings together multiple downstream entities, known as Episode Initiators, is a Convener Participant. A Convener Participant coordinates among its Episode Initiators and bears, as well as apportions, financial risk. Conversely, a participant that is an Episode Initiator, one that solely bears financial risk for itself and not on behalf of other Episode Initiators, is a Non-Convener Participant.

The Model Performance Period for BPCI Advanced will run from October 1, 2018 through December 31, 2023, after which there will be a formal, independent evaluation to assess the program result.

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OIG Issues Advisory Opinion on Neurosurgeon-Hospital Gainsharing Arrangement

The Office of Inspector General of the Department of Health and Human Services (OIG) recently issued an advisory opinion regarding an arrangement whereby a hospital will share with a group of neurosurgeons savings that are realized by implementing certain cost-reduction measures for select spinal fusion surgeries performed at the hospital. While acknowledging the arrangement potentially implicates the federal Anti-Kickback Statute and the portion of the Social Security Act that proscribes civil monetary penalties for certain gainsharing arrangements between hospitals and physicians (the Gainsharing CMP), the OIG was satisfied that the methodologies of the arrangement reduce the risks associated with the Gainsharing CMP and the federal Anti-Kickback Statute, and thus the OIG will not impose sanctions.

The parties to the arrangement include a hospital, a subsidiary of the hospital, a multi-specialty medical practice, and a third-party administrator. Under the arrangement, the hospital, through its subsidiary, will pay neurosurgeons who are part of the multi-specialty medical practice and who meet certain other criteria a share of three years of cost savings attributable to changes made by the neurosurgeons in selecting and using products during spinal fusion surgeries, including changes in the use of Bone Morphogenetic Protein (BMP) and standardization of devices and supplies used during surgery. The arrangement includes certain safeguards such as monitoring and documentation requirements to ensure patient services will not be unnecessarily limited, and established procedures for the use of BMP and the selection of devices and supplies for use during procedures. Under the arrangement, the administrator will be paid a flat monthly fee.

The OIG determined that the methodology used to develop the cost savings, the monitoring and documentation requirements, and the methodology used to calculate the yearly savings, taken together, sufficiently reduce the risk that shared savings payments will induce the neurosurgeons to reduce or limit medically necessary services, and thus the OIG will not impose sanctions under the Gainsharing CMP.

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Connecticut Recognizes Cause of Action for Unauthorized Disclosure of Confidential Medical Information

The Connecticut Supreme Court, in *Byrne v. Avery Center for Obstetrics and Gynecology, P.C.*, recently determined that HIPAA does not preempt (override) state tort actions resulting from unauthorized disclosure of medical information, even though HIPAA does not permit a private cause of action. In addition, the court ruled that HIPAA may set the standard of care for confidentiality in negligence actions: "[T]o the extent it has become the common practice for Connecticut health care providers to follow the procedures required under HIPAA in rendering services to their patients, HIPAA and its implementing regulations may be utilized to inform the standard of care applicable to such claims arising from allegations of negligence in the disclosure of patients' medical records pursuant to a subpoena."

This case adds to the growing consensus of state courts ruling that HIPAA has created the standard of care for protection of medical information and, further, that HIPAA creates a floor, and not a ceiling, for confidentiality protections. State or federal laws providing stricter standards must be followed.

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SAMHSA Revises Confidentiality Rules for Substance Use Disorder Treatment Facilities

Last month, the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), published a final rule making changes to SAMHSA's regulations governing the Confidentiality of Substance Use Disorder Patient Records found at 42 C.F.R. Part 2 (the "Part 2 Rules"). This final rule follows last year's final rule that made broad, sweeping changes to the rules. SAMHSA states the new changes, effective February 2, 2018, "are intended to better align the regulations with advances in the U.S. health care delivery system while retaining important privacy protections for individuals seeking treatment for substance use disorders." 83 Fed. Reg. 239 (1/3/18).

Major provisions of the final rule include revisions to the Part 2 Rules:

- Permitting two different notices accompanying disclosures with patient consent, a longer notice or a shorter notice (to assist users of electronic health record systems to fit the notice in EHR text fields)
- Permitting additional disclosures of patient identifying information, with patient consent, to facilitate payment and health care operations such as claims management, quality assessment, and patient safety activities
- Permitting additional disclosures of patient identifying information to certain contractors, subcontractors, and legal representatives for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation (under the audit and evaluation provisions of the regulations)
- Substance use disorder treatment facilities subject to the requirements of the Part 2 Rules must revise their confidentiality program policies and procedures to incorporate the changes. If you need assistance in reviewing and revising your organization's policies and procedures under the Part 2 Rules, please contact us.

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STATE UPDATE

Amendments to Screening and Diagnostic Medical Testing Regulations Adopted

Effective January 2, 2018, the State Board of Medical Examiners (BME) adopted amendments to the regulations governing screening and diagnostic medical testing in practitioner offices (N.J.A.C. 13:35-2.6). The amendments delineate separate standards for direct requests for specific diagnostic tests and those for referrals for evaluation to determine the appropriate diagnostic tests, and clarify the respective obligations borne by the referring practitioner, the requesting practitioner, and the consulting practitioner. The amendments set forth the respective obligations for practitioners directly requesting tests or referring patients for evaluation, practitioners performing or supervising the performance of the diagnostic tests, practitioners managing diagnostic offices, and practitioners owning diagnostic or screening offices. The following are some key highlights of the amendments:

- The practitioner who makes the request for a specific diagnostic test is responsible for determining the medical necessity for the specifically requested test and the way in which the test results will inform treatment decisions.
- A practitioner with a financial interest or investment in a diagnostic or screening office must ensure that the office is wholly owned through an authorized business structure. Specifically, the regulations require that ownership must be comprised of practitioners or practitioners with closely allied health professionals, so long as the majority interest is held by practitioners who are authorized to perform and interpret all the tests offered at the diagnostic or screening office.
- A practitioner responsible for the management of a diagnostic office must ensure that timely notification is provided to a patient, or the requesting or referring health care professional, of results or the need to repeat the test.
- A trained radiologic technologist may administer a diagnostic test with contrast if a physician or physician assistant or advanced practice nurse is present in the office, except when there is a documented emergency.
- A trained radiologic technologist may administer diagnostic tests, which are not invasive, not conducted with anesthesia or contrast, or which do not require sequential analysis, such as plain film radiology, with a supervising physician immediately available by telephone or other electronic means, if not in the office suite.
- A practitioner who refers a patient for evaluation is required to provide an indication of prior testing or ancillary studies relating to the medical condition and results thereof. This facilitates the testing practitioner's ability to provide appropriate patient care.
- A practitioner who accepts a referral for the evaluation and the determination as to the appropriate diagnostic test shall institute a procedure to assure that sufficient clinical data has been provided to assist in determining the appropriateness of testing, determining which tests to perform, and generating the clinical information necessary to inform treatment decisions.

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Surgical Practice Licensure Bill Signed into Law

On January 16, 2018, bill A4995/S278 was signed into law by then-Governor Chris Christie, requiring surgical practices to apply for licensure as ambulatory care facilities. The bill provides that a surgical practice that is in operation on the date of enactment of the bill will be required to apply for licensure by the Department of Health as an ambulatory care facility licensed to perform surgical and related services within one year of the date of enactment of the bill. Key provisions of the bill include the following:

- Facilities required to apply for licensure under the bill will be exempt from the current initial and renewal license fees.
- A surgical practice that is certified by the Centers for Medicare and Medicaid Services (CMS) will not be required to meet the physical

plant and functional requirements specified in the New Jersey ambulatory care facilities regulations.

- A surgical practice that is not Medicare certified, but which has obtained accreditation from the American Association of Ambulatory Surgery Facilities or any accrediting body recognized by CMS, will not be required to meet the physical plant and functional requirements specified in the New Jersey ambulatory care facilities regulations.
- An additional exception to the prohibition against licensure of new ambulatory care facilities was included in order to permit the issuance of new licenses in the case of: two or more registered surgical practices combining to create a newly licensed ambulatory surgical facility; one or more registered surgical practices combining with a licensed ambulatory surgical facility; or two or more ambulatory surgical facilities combining. In all such cases, the exception is conditioned on the total number of operating rooms in the combined or new facility not exceeding the total number of operating rooms at the practices and facilities prior to the combination of the practices or facilities.
- A surgical practice required to be licensed pursuant to the law will be exempt from the ambulatory care facility assessment; except that, if the entity expands to include any additional room dedicated for use as an operating room, in circumstances where this is permitted by law, the entity will be subject to the assessment.
- The current exception to the prohibition against physician self-referrals was revised to provide that it applies to ambulatory surgery or procedures "involving the use of any anesthesia" subject to certain conditions. The previous exception was limited to ambulatory surgery or procedures "requiring the use of anesthesia."

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New Jersey Legislative Update

***Substance Use Disorder Bill Approved*—**On January 8, 2018, A4707/S2964 was signed into law by then-Governor Christie. The law prohibits residential substance use disorder treatment facilities and after-care facilities (including sober living homes and halfway houses) from denying admission to a person on the basis that the person is currently receiving medication-assisted treatment for a substance use disorder (e.g., methadone, buprenorphine, naltrexone), provided the treatment is administered by a licensed treatment provider.

***Bill Licensing Radiologist Assistants Approved*—**On January 8, 2018, bill S3237/A4871/A4810 was signed into law by then-Governor Chris Christie. The law amends the Radiologic Technologist Act to provide for the licensure and registration of radiologist assistants by the Radiologic Technology Board of Examiners, in the Department of Environmental Protection. The law also provides for the approval by the State Board of Medical Examiners of delegated fluoroscopic procedures that a radiologist assistant may perform, and the establishment of the level of supervision by a licensed radiologist necessary for the radiologist assistant to perform those procedures.

***Bill for Licensure of Ambulatory Care Facilities to Provide Integrated Primary Care Services Approved*—**On January 16, 2018, bill S1710/A3475 was signed into law by then-Governor Christie. Among other things, the law requires the Department of Health to establish a single license for facilities providing integrated behavioral and physical health care.

***Bill Entering New Jersey in Physical Therapy Licensure Compact Approved*—**On January 16, 2018, bill S2511/A4368 was signed into law by then-Governor Christie, entering New Jersey in the Physical Therapy Licensure Compact (PTLC). The PTLC provides for a mutual recognition model of physical therapy licensure (for physical therapists and physical therapist assistants), in which a physical therapist or physical therapist assistant only needs to obtain one license from the state of residence in order to be permitted to practice in any other state that is a party to the compact, as long as the physical therapist or physical therapist assistant complies with the state practice laws of the state in which the patient is located at the time that care and services are rendered.

***Autumn Joy Stillbirth Research and Dignity Act Regulations Adopted*—**Effective January 16, 2018, the Department of Health (DOH) adopted new regulations to implement the Autumn Joy Stillbirth Research and Dignity Act. The Act requires the DOH to establish protocols that are to be followed by health care facilities providing obstetrics and newborn services that would ensure the dignified and sensitive treatment of a patient and family experiencing a stillbirth, which is an unintended fetal death that occurs after 20 weeks of pregnancy or involves the unintended death of a fetus weighing 350 or more grams.

***Sepsis Regulations Adopted*—**Effective January 16, 2018, the Department of Health adopted new regulations to require hospitals to establish, implement, and periodically update, evidence-based protocols (sepsis protocols) for the early identification and treatment of patients in various levels of sepsis (sepsis and septic shock), and to train staff with clinical responsibilities in the sepsis protocols.

***Screening and Screening Outreach Program Regulations Amended*—**Effective January 16, 2018, the Division of Mental Health and Addiction Services adopted amendments to the screening and screening outreach program regulations. The amendments delineate the standards and procedures for determining whether a consumer in need of involuntary commitment to treatment should be assigned to outpatient or inpatient treatment, and permit certain telepsychiatry services.

***After-Care Assistance Regulations Adopted*—**Effective January 16, 2018, the Department of Health adopted new regulations requiring hospitals to offer patients who are able to return to their place of residence after discharge an opportunity to designate caregivers to perform after-care assistance tasks and to train these designated caregivers to competently perform post-hospital care as set forth in the patients' discharge plans.

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Brach Eichler In The News

John D. Fanburg was named a top health care transaction lawyer of 2017 by *The Ambulatory M&A Advisor*.

John D. Fanburg wrote in *Law360* about health care trends to watch in NJ in 2018. John also commented in *Law 360* on the effects of NJ's recent charity care ruling.

Mark Manigan commented in *ROI-NJ* and *NJBIZ* about the effects of NJ's new "one-room" ASC law.

John D. Fanburg and **Mark Manigan** were quoted in *ROI-NJ* and *NJBIZ* on the new health care plan created by Amazon, JPMorgan Chase and Berkshire Hathaway.

John D. Fanburg and **Charles X. Gormally** commented on legal cannabis in NJ in the following publications: *Forbes, NJBIZ, ROI-NJ,* and *The Record*.

Joseph M. Gorrell and **Matthew Collins** wrote in *Becker's Hospital Review* about the greater scrutiny on prescribers and employers as a result of the opioid epidemic.

Lani M. Dornfeld wrote in *Florida Medical Business* about a recent Florida Supreme Court decision concerning Florida's restrictive covenant law.

To view a full listing of recent news items and to read the articles mentioned above, please visit *http://bit.ly/2tYYFha*.

HIPAA CORNER

Medical Record Provider Files Suit to Block Medical Record Fee Limits

Ciox Health has filed suit seeking declaratory and injunctive relief against the Department of Health and Human Services (HHS) to prevent the agency from enforcing parts of HIPAA and the HITECH Act relating to medical record requests. Generally, HIPAA requires a covered entity to provide an individual with access to the individual's protected health information (PHI) in the form and format (paper or electronic) as requested by the individual. The provider may charge only a reasonable, cost-based fee which may only include: (1) labor for copying; (2) supplies (paper or electronic media); (3) postage; and (4) preparation of a summary of the PHI if requested and agreed to by the requester. The fee may not include any costs associated with verification, documentation, retrieval, storage, or infrastructure related to the records. The case, Ciox Health LLC v. Hargen et. al., case number 1:18-cv-0040, was filed in the U.S. Court for the District of Columbia on January 8, 2018.

Ciox is a health care information management company that assists providers with responding to medical record requests. Ciox argues that HHS's 2013 regulations and 2016 guidance are in contravention of HIPAA and HITECH and impose a substantial burden on providers and the medical records industry. In 2013, HHS promulgated a new set of regulations under HITECH requiring providers to provide records regardless of whether the PHI was in an electronic format and in any format requested. Ciox argues that HITECH applies only to electronic records and personal use requests and points to HHS's own admission that these new regulations are overreaching and inconsistent with HITECH.

In 2016, HHS issued guidance stating that providers could charge only the statutory limited rate for all medical record requests, rather than only medical record requests for personal use. Ciox argues that it is clear from Congress' intent and industry standard for over a decade that the fee limitations applied only to requests for personal use and not for records requested by third parties such as life insurance companies and for-profit law firms. Ciox argues that providers and their business associates should not bear the burden of subsidizing these private businesses.

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