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HEALTH LAW DISPATCH

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Continued Implementation of CMS's Price Transparency Rule

By Meghan V. Hoppe, Esq.

A new price transparency rule, promulgated by the Centers for Medicare & Medicaid Services ("CMS"), requires hospitals to publish in a consumer-friendly format on their website a price list for 300 "shoppable services," as well as a list of its standard charges for all items and services provided by the hospital. This transparency is intended to make it easier for consumers to compare prices across hospitals and estimate the cost before seeking care, effectively eliminating surprise medical bills.

The rule defines a "shoppable service" as a health care service that consumers can schedule in advance, such as routine care provided in non-urgent situations. There are five standard charges that must be included in the online pricing information: (1) gross charge; (2) discounted cash price; (3) payer-specific negotiated charge; (4) de-identified minimum negotiated charge; and (5) de-identified maximum negotiated charge.

The rule includes methods to monitor compliance, such as CMS audits of hospitals' websites, and mechanisms to address a finding of noncompliance. If hospital is found to be noncompliant, CMS can: (1) provide a written warning notice to the hospital of the specific violation; (2) request a corrective action plan if noncompliance constitutes a material violation of one or more requirements under the rule; and/or (3) impose a civil monetary penalty not to exceed $300 per day. CMS began auditing a sample of hospital websites in January 2021 to ensure compliance with these new price transparency requirements.

In addition to auditing hospitals for compliance, CMS is also investigating public complaints that are submitted to the agency, which may result in penalties for the hospitals. Consumers may submit an online complaint to CMS if they cannot find a hospital's standard charges, which will assist CMS in identifying noncompliant hospitals throughout the country. The online complaint form strongly recommends that consumers first contact the hospital to ensure applicability before escalating to CMS.

After the rule was first announced in 2019, the American Hospital Association and other industry associations filed suit under the premise that the rates paid by third party payers are proprietary and confidential to both the hospitals and the commercial health insurers, and that their public disclosure would eliminate any ability to negotiate such pricing at arms' length. However, after being upheld by the U.S. Court of Appeals for the District of Columbia Circuit in a December 2020 decision, the new price transparency rule went into effect on January 1, 2021.

There were, notably, no waivers or hardship exemptions to compliance since CMS previously delayed the effective date by one year to provide hospitals with sufficient time to collect and display the required information. Nevertheless, in a recent publication assessing compliance with the new price transparency rule, Health Affairs found that out of 100 hospitals sampled 65 were clearly noncompliant. This evidences the continued need for hospitals to evaluate their compliance efforts and ensure that consumers can easily access the required information.

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OCR Extends Comment Period on HIPAA Rulemaking Proposal

By Deborah A. Cmielewski, Esq.

The U.S. Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") has announced a 45-day extension

to the comment period on the Notice of Proposed Rulemaking ("NPRM") to modify the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"). The comment period, which was initially scheduled to expire on March 22, 2021, will conclude on May 6, 2021 at 5:00 p.m.

The NPRM, which is part of the HHS' Regulatory Sprint to Coordinated Care, aims to promote the sharing of health information and coordination of patient care. The NPRM seeks to (i) expand a covered entity's ability to disclose protected health information ("PHI") in certain emergency circumstances; (ii) broaden a covered entity's ability to disclose PHI to avert a threat to health or safety; (iii) modify the definition of "health care operations"; (iv) permit covered entities to share PHI with certain third parties that provide or coordinate health-related services; (v) facilitate an individual's right of access to his or her own health information: (vi) eliminate the requirement to obtain a patient's acknowledgment of receiving a Notice of Privacy Practices; and (vii) permit the disclosure of patient information to Telecommunications Relay Services ("TRS"). A complete copy of the NPRM is available here.

The NPRM was initially posted on the Federal Register website on January 19, 2021 and the Office of the Federal Register published the NPRM in the Federal Register on January 21, 2021. On January 20, 2021, the White House issued a Regulatory Freeze Memorandum to provide new appointees the ability to review new and pending rules prior to further implementation. In addition to directing new rules to be placed on hold and pending rules to be withdrawn, the Memorandum directed Executive Department and Agency heads to consider extending for 60 days the effective date of rules already published in the Register. The OCR has issued the 45-day extension to clarify that the NPRM remains available for public comment despite the Regulatory Freeze Memorandum and to allow sufficient time to receive meaningful input from interested stakeholders.

For more information regarding the NPRM, contact Deborah A. Cmielewski, Esq. at dac@spsk.com or 973-540-7327.

Medicare Coverage of Innovative Technology Final Rule Delayed

By Daniel O. Carroll, Esq.

The Centers for Medicare & Medicaid Services' ("CMS") final rule establishing the Medicare Coverage of Innovative Technology ("MCIT") pathway to Medicare coverage for breakthrough medical devices and related medical procedures ("Final Rule"), which was published on January 14, 2021 and slated to become effective as of March 15, 2021, will not become effective until at least May 15, 2021, in order to allow CMS to consider additional comments and issues of fact, law and policy. This delay is made in accordance with the January 20, 2021 memorandum from Ronald Klain, Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review". This delay and request for additional comments now causes uncertainty about whether or not the Final Rule (as published) will actually become effective on May 15, 2021.

The Final Rule is intended to address the current significant delay between the Food and Drug Administration's ("FDA") marketing approval for innovative medical devices that are designated as part of the Breakthrough Devices Program and Medicare coverage of the same. The MCIT pathway will provide Medicare coverage for Breakthrough Devices and related medical procedures during a four-year period that begins immediately upon FDA marketing authorization. The Final Rule also codifies the phrase "reasonable and necessary" in order to provide greater certainty for those seeking coverage for Part A and Part B items and services (including FDA designated Breakthrough Devices after the initial four-year period of MCIT coverage).

A medical device is eligible to be designated by the FDA as a "Breakthrough Device" if it (a) provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions, and (b) meets at least one of the following: (i) represents breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) offers significant advantages over existing approved or cleared alternatives, or (iv) device availability is in the best interests of patients. Designation as a Breakthrough Device is intended to provide manufacturers with a way to expedite the development and availability of the device in coordination with the FDA.

However, currently, FDA marketing approval does not automatically result in Medicare coverage. Under the MCIT

pathway, Medicare coverage can begin immediately on the date of FDA marketing approval for the Breakthrough Device or on a later date designated by the manufacturer. Such coverage is available unless the Breakthrough Device does not have a Medicare benefit category or is otherwise excluded from coverage by statute. The MCIT pathway is voluntary for manufacturers who opt-in. The MCIT coverage expires four years after the date of FDA approval (whether or not the manufacturer requests coverage to begin at a date after the date of FDA approval).

If available, Medicare coverage under the MCIT pathway includes coverage for (a) the Breakthrough Device, (b) any reasonable and necessary procedures to implant and/or use the Breakthrough Device, (c) any reasonable and necessary items and services to maintain the Breakthrough Device, (d) related care and services for the Breakthrough Device, and (e) reasonable and necessary services to treat complications arising from use of the Breakthrough Device.

Additional comments on the Final Rule are due April 16, 2021, after which CMS will have one month to consider whether to allow the Final Rule should be amended, rescinded, further delayed or allowed to become effective.

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Expert Evidence Needed to Prove Emotional Distress Claims

By Benjamin A. Hooper, Esq.

The Appellate Division recently addressed the need for medical and expert testimony to establish an actionable claim of negligent infliction of emotional distress in the published opinion Clark v. Nenna, 2020 N.J. Super. 244 (App. Div. 2020).

The plaintiff, a paraplegic, required surgery, including placement of screws and washers to stabilize a broken femur. The defendant orthopedic surgeon subsequently performed a second surgery to remove the screws; however, the washers remained embedded in the scar tissue that developed around the hardware. The surgeon claimed to have intentionally decided against removing the washers because removal would have required a larger incision, increasing the risk of postoperative infection. The orthopedic surgeon did not document the chart to memorialize the retained washers; did not discuss during the pre-surgical consult the potential for retaining the washers; and following the surgery, did not disclose the decision against removing the washers. Plaintiff first learned of the retained washers four (4) years later when he underwent an x-ray of the leg for unrelated medical concerns.

The patient brought suit contending that it was a deviation from the standard of care to fail to remove the washers from the leg. Although plaintiff-patient served an expert liability report, the surgeon moved for summary judgment seeking to dismiss the case on the basis that the plaintiff failed to demonstrate damages resulting from the retained washers. In response, plaintiff cited the mental anguish caused by the knowledge of a foreign object in his body, coupled with the knowledge that he could not undergo another surgery to remove the retained washers. Plaintiff acknowledged that his claimed damages were limited to emotional distress. The trial court granted summary judgment, ruling that plaintiff had failed to establish compensable damages, and an appeal followed.

On appeal, the Appellate Division agreed that the plaintiff failed to demonstrate compensable damages based on emotional distress. The Court ruled that for a claim of direct negligent infliction of emotional distress to be viable, a plaintiff must demonstrate that he suffered from severe or genuine and substantial emotional distress. Severe emotional distress is defined as the type of severe and disabling emotional or mental condition generally recognized and diagnosed by a mental health professional. Emotional distress claims cannot be based on speculation. Vague complaints, such as lack of sleep, aggravation, headaches and depression are deemed insufficient as a matter of law. Because of the potential for fabricated claims, the Court ruled that medical evidence or expert testimony is needed to substantiate a claim of emotional distress and is a prerequisite to allow the jury to decide whether the claim has in fact been proven.

The Court's opinion acknowledged the existence of claims where courts find that the nature of the harm would have cause any reasonable person "severe" or "genuine and substantial" emotional distress, mitigating against the need for expert testimony to substantiate the claim. Such examples include claims for willful discriminatory conduct which necessarily include humiliation and indignity and claims of wrongful birth arising from inadequate genetic counselling.

In applying the law, the Court reasoned that where the nature of the harm would be expected to cause severe genuine substantial emotional distress, plaintiffs must support their claims for damages with medical evidence or expert proof. The Appellate Division did not find that the alleged emotional distress caused by the professional negligence of a surgeon failing to remove surgical washers from a leg presented a peculiar likelihood of emotional distress, necessitating medical or expert proof as a matter of law.

This published Appellate Division opinion places plaintiffs in medical negligence cases on notice that they must proffer expert testimony to establish a direct claim for negligent infliction of emotional distress.

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