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Health Care Regulatory and Legislative Update

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Medical Device Manufacturer Pleads Guilty to Misbranding and Agrees to Pay $36 Million to Resolve Criminal Liability and False Claims Act Allegations

On November 7, 2016, the Department of Justice (*"DOJ"*) announced that Pennsylvania-based medical device manufacturer Biocompatibles Inc. pleaded guilty to misbranding its embolic device LC Bead — a device used to treat liver cancer and other diseases — in violation of the Food, Drug and Cosmetic Act. According to the DOJ press release, sales representatives for the company told health care providers that the medical device increased the level of chemotherapy delivered to a liver tumor and resulted in "better tumor response rates," despite the lack of FDA clearance or approval for that use and despite the absence of statistically significant evidence to support such claims. Biocompatibles will pay more than $36 million to resolve criminal and civil liability arising out of its illegal conduct. This settlement highlights the importance of the continued monitoring of your Company's sales representative's activity and materials.

Federal District Court Blocks CMS Rule Banning Pre-Dispute Binding Arbitration Clauses in Nursing Home Contracts

A federal district court in Mississippi has granted a preliminary injunction preventing a Centers for Medicare & Medicaid Services (*"CMS"*) rule prohibiting any nursing home that accepts Medicare or Medicaid funds from including pre-dispute arbitration clauses in resident contracts. The rule was initially slated to take effect as of November 28, 2016. The

temporary injunction was granted at the request of the American Health Care Association (*"AHCA"*), a nursing home industry group, and four other state and local health care groups, which argued that the CMS rule was impermissible overreach of a federal agency. CMS argued that the rule was necessary to protect vulnerable, and sometimes mentally incompetent, seniors. In its over 40 page order, the federal district court concluded that while the court was in "the undesirable position of preliminarily enjoining a rule which it believes to be based on sound public policy," it was "unwilling to play a role in countenancing the incremental 'creep' of federal agency authority." Although the order indefinitely postpones the rule from taking effect until the lawsuit is settled, nursing home administrators should be prepared to revise form admission agreements to remove binding arbitration provisions and otherwise comply with the final rule, which can be found here. We will continue to monitor the outcome of this legislation.

CMS Releases CY 2017 Final Rule Implementing Changes to Medicare Outpatient Prospective Payment System

On November 1, 2016, CMS finalized updated payment rates and policy changes in the Hospital Outpatient Prospective Payment System (*"OPPS"*) and Ambulatory Surgical Center (*"ASC"*) Payment System for calendar year (*"CY"*) 2017. With this final rule, CMS makes three notable changes to the OPPS:

1. It removes the pain management dimension of the Hospital Consumer Assessment of Healthcare Providers and Systems Survey for purposes of the Hospital Value-Based Purchasing Program to address physicians' concerns that the pain management patient survey questions created financial incentives to overprescribe pain medication.
2. It implements the mandate of the Bipartisan Budget Act of 2015 to eliminate hospital incentives to purchase physician practices and convert them to off-campus outpatient provider-based departments (*"OPDs"*). Currently, Medicare pays for the same services at a higher rate if those services are provided in a hospital OPD rather than a physician's office. CMS has noted that this payment differential provided an incentive for hospitals to acquire physician offices in order to receive the higher rates. The final rule describes which off-campus hospital OPDs are subject to the requirement that certain items and services furnished by certain off-campus hospital OPDs will no longer be paid under the OPPS beginning January 1, 2017, and which items and services are "excepted" from application of these payment changes and will continue to be paid under the OPPS.
3. It modifies the Medicare and Medicaid Electronic Health Record Incentive Programs to increase flexibility and reduce administrative burdens, so that providers can focus on the exchange of health information and use of technology to support patient care.

The official copy of the final rule is expected to be published in the Federal Register on November 14, 2016. Until then, an unofficial copy is available here. A fact sheet on the final rule is available here.

Fewer Hospitals to Receive Value-Based Purchasing Program Bonuses in 2017

On November 1, 2016, CMS released its most recent round of results for its Hospital Value-Based Purchasing Program (*"HVBP Program"*), a program mandated by the Affordable Care Act which financially rewards or penalizes hospitals based on the quality of care provided to Medicare patients. The federal data shows that for fiscal year 2017, more than 1,600 hospitals will receive bonuses — approximately 200 fewer than received bonuses last year. The number of hospitals that will receive financial penalties grew by approximately 100 hospitals.