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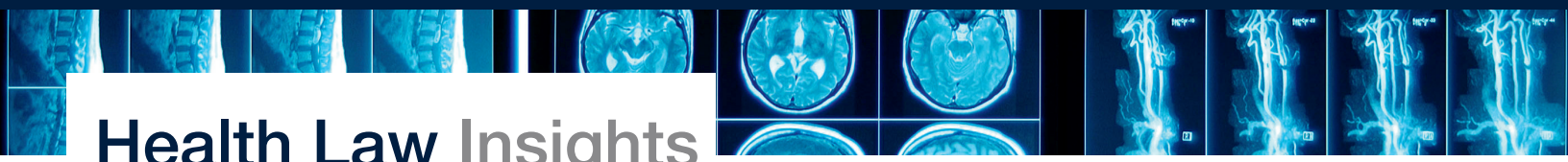

Health Law Insights

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CMS Proposes Bundled Payments for Cardiac Care

In its most recent effort to hasten Medicare's transformation from a fee-for-service payment model to a value-based payment model, the Centers for Medicare & Medicaid Services (CMS) proposed on July 25 a new mandatory bundled payment model for cardiac care services and an extension of the existing bundled payment model for hip replacements to include other surgeries for hip and femur fractures.

If the proposed rule is finalized, the new cardiac bundled payment model would launch on July 1, 2017, in 98 randomly selected metropolitan statistical areas, and the expansion of the Comprehensive Care Joint Replacement model would occur in the 67 MSAs already participating in the model.

Under the proposal, Medicare would pay hospitals a fixed amount, or target price, per episode of care for beneficiaries admitted for a heart attack, bypass surgery or surgical hip/femur fracture treatment. CMS would set target prices for different episodes of care on the basis of historical costs for Medicare fee-for-service beneficiaries, which would then be adjusted according to the complexity of the particular episode of care. The central tenet of the proposed models lies in the shifting of accountability to the admitting hospital for the cost and quality of care provided to the patient during the treatment episode, encompassing the inpatient stay and 90 days after discharge.

At the end of a performance year, actual spending for the episode, including aggregate expenditures for Medicare Parts A and B, would be compared to the fixed per-episode target price calculated for the responsible hospital. Hospitals that collaborate with physicians and other providers to provide care at a cost lower than the target price would receive the difference between the target price and actual costs, while hospitals with costs exceeding the target price would be required to repay Medicare. Furthermore, hospitals that deliver higher-quality care would be eligible to be paid a higher amount than those with lower-quality performance.

The proposal includes a phased implementation mechanism whereby gains would be capped at 5% during the first two performance periods, increase to 10% in the third performance period and plateau at 20% in 2020 and 2021, the last two years of the program. With respect to downside risk, participants would incur no repayment penalty during the first performance period and the first quarter of the second year. For the balance of the second year, downside risk would be capped at 5%, increasing to 10% in 2019 and 20% in 2020 and 2021. The first performance period would run from July 1, 2017, to December 31, 2017, while the second through fifth performance periods would correspond to calendar years 2018 through 2021.

Hospital groups have expressed concerns over the rapid pace that CMS is setting for the implementation of these transformative bundled payment models. American Hospital Association Executive Vice President Tom Nickels observed in a statement that the proposed cardiac care model "is the third mandatory demonstration project from CMS in a little over a year." Nickels added, "CMS is putting the success of these critical programs at risk. Hospitals are under a tremendous burden to help ensure these complex models will work for patients."

The proposed rule was published in the August 2, 2016, *Federal Register*. The comment period closes on October 3, 2016.

Prescription Drug Prices Are Not a Significant Driver of 2017 Premium Increases

The description by many health care commentators of high pharmaceutical prices as the most significant driver in insurance premium hikes may be misdirected, according to a report released by Avalere Health on August 2. Avalere's analysis of proposed rate filings for nine states found that drug costs were responsible for only about 14% of health insurers' premium justifications for 2017, whereas drugs accounted for approximately 18% of insurance claims in 2015. Normally, insurers' premium requests track the insurers' claims experience from prior years.

Accounting for about 30% of 2017 rate increase requests, outpatient spending – not pharmaceutical costs – is anticipated to be the largest driver of premium hikes. The analysis also found that insurers expect professional services to account for about 28% of claims in 2017 and that costs for inpatient care will contribute 15.4% to 2017 premium increases.

While the Avalere analysis emphasizes the decreased percentage of 2017 premium increases attributable to drug costs relative to 2015, Michael Taggart of Milliman, Inc., explained in an August 3 statement to Bloomberg BNA that claim costs for 2015 and 2016 already reflect a significant increase in drug costs. "They're not going to assume that there's another year with percentage increases as big," he noted. "It's already baked into their starting numbers."

Though analysts may disagree on the extent to which drug prices are contributing to rising insurance premiums, the Avalere Health analysis makes it clear that no single health industry stakeholder is primarily responsible for increases.

Medicare Readmission Penalties Hit Record High as CMS Expands Criteria

In its final rule on the inpatient prospective payment system, the Centers for Medicare & Medicaid Services (CMS) announced on August 2 a record increase in readmission penalties under the Hospital Readmission Reduction Program (HRRP) and an expansion of the program to readmissions following coronary artery bypass graft surgery. The HRRP penalizes hospitals for readmissions of beneficiaries with certain conditions within 30 days of discharge.

CMS estimates that it would penalize 2,588 hospitals, constituting more than half the nation's hospitals, for excessive admission rates in fiscal year 2017. Although this is approximately the same number penalized last year, the average penalty will increase by a fifth, according to a Kaiser Health News analysis, from 0.61% to 0.73%, for a total of $528 million, about $108 million more than last year. CMS estimates that 49 hospitals will receive the maximum penalty of a 3% reduction in Medicare reimbursements.

Payment cuts under the HRRP apply to all Medicare patients, not just to beneficiaries with conditions subject to readmission penalties. Such conditions include myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, hip and knee replacements and – new for 2017 – coronary artery bypass graft surgery.

As explored in an article by McCarter & English attorneys Justin Linder and Dennis Barrett that was published in *AHLA Connections* in March, the imposition of increased readmission penalties comes amid a simmering debate among health care policymakers over how to appropriately address the influence of sociodemographic status on readmission rates. Currently, CMS does not consider the challenges faced by hospitals serving low-income patient populations that have trouble affording the medications or implementing the lifestyle changes required to recover from conditions subject to readmission penalties. Although the CMS final rule once again declines to adjust penalties to account for such factors, there are a number of initiatives, outlined in the article by Linder and Barrett, that hospitals have successfully implemented to reduce readmissions among disadvantaged patient populations.

PhRMA and BIO Release Model Off-Label Promotion Regulations in Face of FDA Inaction

Responding to the continued lack of guidance concerning the sharing by pharmaceutical manufacturers of off-label drug information with payers and providers, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) weighed in with a set of principles released on July 27 that govern the sharing of data and information outside of FDA-approved labeling.

Under the policy of the Food and Drug Administration (FDA), companies can be subject to criminal prosecution and civil liability for promotion of products for indications not specifically approved by the FDA. However, the outcomes of various lawsuits over the past few years have increased uncertainty regarding the enforceability of FDA regulations that biopharmaceutical companies have long critiqued as being overly burdensome and unclear.

The FDA policy has been dealt multiple setbacks in federal lawsuits questioning its constitutionality under the First Amendment. Most recently, Amarin Pharma, Inc., in March reached a settlement with the FDA in a lawsuit challenging FDA off-label promotion regulations on constitutional grounds. Despite the agency's commitment to issue revised guidance by the end of 2014, industry stakeholders continue to await action by the FDA.

The document centers around three key concepts – a commitment to science-based communication, a commitment to providing appropriate context about data and a commitment to accurate representation of data – and nine principles, including the following:

- Companies should provide scientific substantiation if shared information is not contained in FDA-approved labeling;
- Additional science-based information from sources other than FDA-approved labeling helps health care professionals and payers make informed decisions for patients;
- Communications should be tailored to the sophistication of the intended audience;
- Communicating with payers about new medicines and new uses of approved medicines facilitates patient access upon approval; and
- Real-world evidence based on patient experience and pharmacoeconomic information can improve understanding of health outcomes and costs.

PhRMA and BIO released its off-label principles in part to offer perspective on what a modified FDA framework could look like.

Surgeon General Points to Physicians' Role in Combating Opioid Addiction

In an August 8 visit to St. Barnabas Medical Center in Livingston, New Jersey, to participate in a panel discussion, U.S. Surgeon General Vivek Murthy emphasized the important role that physicians must play in fighting the opioid crisis that is having a devastating impact across the country. As reported on August 9 by the *Asbury Park Press*, Murthy, who assumed the office of Surgeon General in 2014, had no idea when he entered medicine that substance abuse would become a defining issue in his career. "When I became a doctor, I assumed I would spend most of my days seeing people with infections, with diabetes, with heart disease and complications from cancer. … What I never imagined was that the majority of my time would be spent thinking about substance use disorders." During the discussion, Murthy also observed that 40% of addicts suffer from mental health problems, and noted the failure of government to effectively address the correlation.

Over the course of his remarks, Murthy promoted Turn the Tide Rx, his office's new initiative to encourage health care providers to become a part of the solution to the opioid crisis. The initiative's website contains information and advice for providers related to proper prescribing of opioids for acute pain therapy, long-term therapy considerations and proper dosages. Among other things, it recommends that "clinicians should prescribe the lowest effective dose of immediate-release opioids for the shortest therapeutic duration. Three days or less will often be sufficient; more than seven days will rarely be needed." The site also contains an opioid overdose toolkit and information about free training and Continuing Medical Education programs for physicians.

Joining Murthy on the panel were David Shulkin, the Undersecretary for Health at the U.S. Department of Veterans Affairs (VA), and New Jersey Senators Cory Booker and Robert Menendez. As reported by the *Asbury Park Press*, Shulkin noted that 60% of veterans returning from conflicts and 50% of older veterans suffer from chronic pain. Despite these high numbers, overall opiate use by veterans dropped 22% after a major initiative was launched in 2013. The initiative enabled the VA to reduce opioid dosages by 32% and the chronic use of opioids by 30%. For his part, Booker claimed that in order to increase the number of beds available to veterans seeking help, he is working to eliminate the cap on Medicaid funding that limits the number of treatment beds to 16 beds per facility.

CMS Highlights Resident Privacy Concerns in Letter to State Survey Agency Directors

The growth of social media platforms has introduced a seemingly endless variety of avenues through which to share pictures and videos with friends and other users. While these platforms have enhanced the ability of users to share information, they also may serve as tools to enable the abuse and exploitation of vulnerable individuals in health care settings. Following a slew of media reports highlighting the inappropriate photographing of residents by nursing home staff in recent years, the Director of the Survey and Certification Group at the Center for Medicare & Medicaid Services (CMS) sent a letter to the directors of state survey agencies on August 5 stressing the responsibilities of facilities and states with respect to the protection of residents.

The letter observes that all nursing home residents have a right to personal privacy of not only their bodies but also their personal space, which includes accommodations and personal care. According to the letter, "taking photographs or recordings of a resident and/or his/her private space without the resident's, or designated representative's, written consent is a violation of the resident's right to privacy and confidentiality."

The letter sets forth examples of impermissible conduct, such as "staff taking unauthorized photographs of a resident's room or furnishings (which may or may not include the resident), or a resident eating in the dining room, or a resident participating in an activity in the common area." Referencing various federal regulations governing staff treatment of residents, nursing aide competency, responses to alleged violations, and requirements for the administration and governing bodies of nursing homes, CMS emphasizes the obligation of nursing homes to train all staff regarding the prohibition on the use of cameras, smart phones and other electronic equipment to take or distribute humiliating or demeaning photographs and recordings of residents. The letter notes that in-service training does not relieve facilities of the responsibility to implement such policies and procedures and that the "nursing home must provide ongoing oversight and supervision of staff in order to assure that these policies are implemented as written." Nursing homes also have an obligation to investigate any allegations of abuse and to report them to the appropriate law enforcement agencies when necessary.

The letter also debuts a set of enhanced state surveyor responsibilities effective as of September. Among these, surveyors must request and review nursing home policies and procedures governing photography and videography by staff members, and in the event of a complaint, surveyors must conduct an on-site investigation to determine whether the nursing home is in compliance with federal regulations. If the surveyor determines that a facility worker violated a resident's rights, the state must report the findings within 10 days to the administrator of the facility where the incident occurred, the administrator of the facility where the worker is currently employed, the responsible worker's licensing authority and, if applicable, the nurse aide registry.

The letter demonstrates that regulators are increasingly attuned to the privacy concerns of nursing home residents and places nursing home administrators on notice that they need to be vigilant in training and in monitoring the activities of their staff.

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