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Health Care Regulatory and Legislative Update

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Weekly Health Care Criminal and Civil Fraud Enforcement Round-Up

The following highlights notable health care fraud and abuse news, settlements and enforcement actions from the previous week.

1. **OIG Investigative Advisory Highlights Continuing Fraud Vulnerabilities in Personal Care Services**. In an Investigative Advisory (*"Advisory"*) issued by the Department of Health and Human Services Office of the Inspector General (*"OIG"*), the OIG indicated that the Centers for Medicare & Medicaid Services (*"CMS"*) needs to "improve its oversight and monitoring of personal care services (*"PCS"*) programs nationwide," especially as individuals increasingly receive care in their communities rather than in institutional settings. PCS is an optional Medicaid benefit that a state may choose to provide for its Medicaid beneficiaries with federal approval. PCS typically include nonmedical assistance (meal preparation, light housework, bathing, etc.) to elderly, people with disabilities and individuals with chronic or temporary conditions. The Advisory noted "significant and persistent compliance, payment, and fraud vulnerabilities in PCS," particularly involving fraud schemes where PCS claimed were either unnecessary or never provided. The OIG urged CMS to implement key safeguards for the PCS program, including: (1) establishing minimum federal qualifications and screening standards for PCS workers, such as background checks; (2) requiring states to enroll or register all PCS attendants and assign them unique numbers; (3) requiring that PCS claims identify the dates of service and the PCS

attendant who provided the service; and (4) considering whether additional controls are needed to ensure that PCS are allowed under program rules and are actually provided. Whether PCS will be highlighted in the OIG's 2017 Work Plan, which is expected out yet this year, remains to be seen. Going forward, providers and lenders in this space should take care that services are properly documented and attendants are properly vetted and trained.

2. **Tenet to Pay $513 Million to Settle Kickback Allegations; Shareholder Files Class Action**. On October 3, 2016, the Department of Justice (*"DOJ"*) announced that Tenet Healthcare Corporation, a large hospital chain, and two of its Atlanta-area subsidiaries (*"Tenet"*) will pay over $513 million to resolve criminal charges and civil claims relating to a scheme to defraud the United States and to pay kickbacks in exchange for patient referrals. The government, joining a whistleblower suit, specifically alleged that Tenet made kickback payments to prenatal clinics under the guise of commissioning translation, marketing and Medicaid eligibility determination services, funneling pregnant women to Tenet hospitals for deliveries. The whistleblower's share in this settlement will be over $84 million. A Tenet shareholder has since filed suit in California federal court alleging that Tenet mislead investors and inflated the company's stock in violation of the Securities Exchange Act.

Vermont Granted Tentative Approval for All Payer Reimbursement System

After nearly two years of negotiation, Vermont has received tentative approval from CMS to proceed with an "all payer" reimbursement model (*"All Payer Model"*). Under an All Payer Model, payers (Medicare, Medicaid and commercial insurers) would contract with health care providers to provide comprehensive care to large groups of patients for a predetermined monthly amount rather than reimbursing them for each test, procedure or visit. Vermont says that the switch from a fee-for-service model to an All Payer Model provides the state an opportunity to (1) improve quality of care by creating financial incentives for doctors and hospitals to keep patients as healthy as possible, (2) reduce the state's health care cost growth — specifically, Vermont aims to limit the state's health care cost growth to 3.5% over the next five years, rather than the projected 6.6%, and (3) address any existing cost shift, which is the tendency by providers to charge private insurers a higher price to make up for lower reimbursement from Medicaid and Medicare.

The State already has the regulatory authority to set reimbursement rates for both Medicaid and commercial payers, but requires final approval from Medicare. The Medicare approval is known as a Medicare "wavier." Under the tentatively approved Medicare waiver agreement, providers would operate under an accountable care organization (*"ACO"*) which would accept reimbursement payments. The ACO would then pay providers based on quality of care provided. Under the initial terms of the Medicare wavier agreement, State officials report that Vermont would receive around $51 million in total Medicare funding between 2017 and 2022, including a $9.5 million one-time investment in 2017 partly to build ACO infrastructure. The waiver also sets a Medicare-specific cost growth target as 0.2% less than the national trend and outlines several statewide measures for improving health outcomes and quality. The agreement still has to be signed by CMS and Vermont officials before it is considered final. The state is conducting public forums on the waiver in the next few weeks.

If approved, the Vermont All Payer Model would be the first in the nation to cover all healthcare providers. Maryland's all payer model only covers hospitals. While Vermont previously considered launching a government "single-payer" insurance system like that proposed by Vermont Senator Bernie Sanders, Vermont gave up its single-payer plans in 2014 after it received estimates that launching the system would cost the state more than $2 billion in 2017 alone.

CMS Issues Final Rule for Long-Term Care Facilities — First Comprehensive Overhaul for Industry in 25 Years

CMS recently released a final rule revising the quality, safety and consumer protection standards that a long-term care facility (*"LTCF"*) must meet to participate in the Medicare and Medicaid programs. The 185-page Final Rule is the first major regulatory overhaul for the LTCF industry since 1991. Some key changes finalized in the rule, as highlighted by CMS, include:

- Strengthening the rights of LTCF residents, including prohibiting the use of pre-dispute binding arbitration agreements.
- Ensuring that LTCF staff members are properly trained on caring for residents with dementia and in preventing elder abuse.
- Ensuring that LTCFs take into consideration the health of residents when making decisions on the kinds and levels of staffing a facility needs to properly take care of its residents.
- Ensuring that staff members have the right skill sets and competencies to provide person-centered care to residents. The care plans developed for residents will take into consideration their goals of care and preferences.
- Improving care planning, including discharge planning for all residents with involvement of the facility's interdisciplinary team and consideration of the caregiver's capacity, giving residents information they need for follow-up after discharge, and ensuring that instructions are transmitted to any receiving facilities or services.
- Allowing dietitians and therapy providers the authority to write orders in their areas of expertise when a physician delegates the responsibility and state licensing laws allow.
- Updating the LTCFs infection prevention and control program, including requiring an infection prevention and control officer and an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

In response to the complexity of the final rule and the financial burden, CMS adopted a three-phase implementation schedule: Phase 1, must be implemented by November 28, 2016, Phase 2 by November 28, 2017, and Phase 3 by November 28, 2019. The three phases have been categorized based on CMS's assessment of the requirement's complexity and the extent to which interpretive guidance will be needed. While CMS has indicated that the final rule took into account some of the nearly 9,800 comments received from industry stakeholders to the proposed version of the rule, the new regulations are still immense, complex and will require significant effort and cost outlays from LTCFs. Whether the three-phase roll-out or future regulatory guidance will ease the transition is yet to be seen.

MedPAC Unsatisfied with Savings Generated by Medicare Shared Saving Program ACOs

In an October 6, 2016 presentation analyzing the 2015 financial results of the Medicare Shared Savings Program (*"MSSP"*) ACOs, the Medicare Payment Advisory Commission (*"MedPAC"*) found that MSSP ACOs have not created substantial savings for the government. The presentation noted that while the MSSP generated $429 million in savings in 2015, the government paid out $646 million to MSSP ACO participants resulting in a $216 million net loss for the program. News outlets report that during the MedPAC meeting, MedPAC Commissioner Craig Sammit, M.D. said that the results were "incredibly unsatisfying." It will be interesting to monitor whether CMS will phase out the MSSP's "one-sided risk" option (meaning that the ACO can share in the savings it generates without taking on the risk of loss) and push more ACOs to take on risk of both savings and losses.