Insights

Health Care Regulatory and Legislative Update

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Health Care Finance

Oncology Practice, Practice Manager and Physician Pay $1.7 Million to Resolve Allegations of Billing Medicare for Unapproved Chemotherapy Drugs

On February 16, 2017, the Department of Justice (*"DOJ"*) announced a $1.7 million civil settlement with The Oncology Practice of Dr. Kenneth D. Nahum (the *"Practice"*), Dr. Nahum and the Practice manager. The settlement resolves allegations that the Practice ordered chemotherapy drugs from a foreign distributor that were not approved by the FDA for sale in the United States. The Practice allegedly administered the infusion drugs to its patients and then billed the Medicare program for both the drugs and the infusion services. Because Medicare will only reimburse for FDA-approved drugs, each claim for reimbursement constituted a false claim under the federal False Claim Act (*"FCA"*). Additionally, Drug Supply Chain Security Act (21 U.S.C. 352 et seq.) requires all health care providers who dispense or administer prescription drugs to patients to purchase their prescription drug products only from authorized trading partners licensed by and/or registered with the state or Federal government, as applicable. This settlement is just one in an increasing number of civil and criminal convictions against physician practices that purchase and administer unapproved drugs and highlights that physicians are ultimately responsible for knowing the source of any drugs administered to their patients.

Federal Regulators Issue Proposed Rule Aimed at Stabilizing Insurance Marketplaces While Future of ACA is Debated; President Trump's "One In, Two Out" Executive Order Determined Inapplicable

On February 15, 2017, the Centers for Medicare & Medicaid Services (*"CMS"*) issued a Proposed Rule aimed at stabilizing the Affordable Care Act's (*"ACA"*) health insurance exchange markets (*"Markets"*) while the future of the ACA is debated. As widely reported, the Markets have been plagued by insurer exit and increasing premiums in many geographic areas. To improve risk pools and promote stability within the Markets, CMS proposes four actions to increase incentives for individuals to maintain insurance and decrease the incentives for individuals to enroll only after they discover an adverse health condition (known as Adverse Selection):

1. **Shortened Enrollment Period.** In response to insurer concerns regarding partial year coverage and Adverse Selection, CMS proposes shortening the open enrollment period from three months (November through end of January) to six weeks (November through December 15). CMS anticipates this will improve the risk pool by reducing Adverse Selection opportunities in late December and January and encouraging healthier individuals who might have previously enrolled in partial-year coverage after December 15 to instead enroll in full year coverage.
2. **Verification of Special Enrollment Events.** In response to insurer concerns of special enrollment period abuse, CMS proposes increasing pre-enrollment verification of eligibility for all special enrollment categories (e.g. — employment change or marriage) from 50 to 100 percent of special enrollment customers. This change would only be required for federally-run health insurance exchanges — those state Markets that are served by the *gov* platform.
3. **Collection of Unpaid Premiums Before Re-Enrollment.** In response to insurer concerns that individuals were "gaming" the Markets by only paying premiums when in need of health care services, CMS proposes revising its interpretation of the ACA's "guaranteed availability" requirement to allow issuers to collect unpaid premiums from customers whose policies were terminated due to failure to pay premiums before having to re-enroll them in the coming year's plan.
4. **Flexibility to Provide Fewer Benefits.** In order to stabilize premiums, CMS proposes allowing insurers greater flexibility in designing new plans by increasing the "actuarial value" (*"AV"*) margin from 2 to 4 percent. CMS estimates that the proposed change in AV could lead to a 1 to 2 percent reduction in premiums, which in turn, would increase enrollment.

Comments on the Proposed Rule, which can be submitted though www.regulations.gov, must be received no later than 5:00 p.m. EST on March 7, 2017

Interestingly, CMS has determined that the Proposed Rule is not subject to President Trump's "One In, Two Out" Executive Order 13771, which requires federal agencies, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. CMS explains that federal guidance on the scope of the Executive Order issued on February 2, 2017 states that for Fiscal Year 2017, the One-In, Two Out Executive Order only applies to each new "significant regulatory action that imposes costs," and that the Proposed Rule does not

meet that threshold. We will continue to monitor whether the One-In, Two-Out Executive Order has teeth in the regulation-heavy health care industry.

House Republicans and Trump Administration File Joint Motion to Indefinitely Delay Resolution of Lawsuit with Potential to Dismantle ACA Insurance Exchanges

On February 21, 2017, the House of Representatives and the Department of Justice filed a Joint Motion in *House v. Price* (formerly *House v. Burwell*) asking the United States Court of Appeals for the District of Columbia to continue to hold the case in abeyance "with status reports due every three months beginning May 22, 2017" in order "to allow time for a resolution that would obviate the need for judicial determination of [the] appeal, including potential legislative action." As a reminder, *House v. Price* is the lawsuit brought by the House of Representatives claiming that the Obama administration was illegally paying marketplace insurers cost-sharing subsidies for low-income beneficiaries because Congress had not appropriated funds. In May 2016, the district court ruled in favor of the House and enjoined future subsidy payments until a forthcoming Congressional appropriation. The district court stayed its injunction pending the administration's appeal, which was filed this past fall. After President Trump was elected, the House asked for additional time to discuss resolution of the case with the Trump administration. While seeking a further delay of its own lawsuit seems counterintuitive, the GOP-controlled House is likely attempting to avoid blame for any insurance market destabilization or collapse that could result by pulling the insurer subsidies without an ACA replacement firmly in place.