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Favorable OIG Advisory Opinion Provides Helpful Roadmap in Structuring a Patient Lodging/Meals Assistance Program That Complies with Federal Law

On March 10, 2017, the Department of Health and Human Services Office of the Inspector General (*"OIG"*) posted a favorable Advisory Opinion (*"Opinion"*) for an academic medical center (*"Medical Center"*) seeking to offer certain patients in rural or underserved areas free or reduced-cost lodging and meals in order to help them access health services they may not be able to obtain locally (*"Proposed Arrangement"*). The Opinion is the first to provide additional guidance with respect to the "Promotes Access to Care Exception" to the Civil Monetary Penalty Law's prohibition against beneficiary inducements (*"Beneficiary Inducement CMP"*), described in the OIG's December 7, 2016 Final Rule (*"Final Rule"*) and previously examined in our December 14, 2016 Health Care Regulatory and Legislative Update.

Based on the facts provided, the OIG determined that the Proposed Arrangement would not constitute grounds for the imposition of penalties under the Beneficiary Inducement CMP, or administrative sanctions under the Anti-Kickback Statute (*"AKS"*). As is the case with all OIG advisory opinions, the Opinion is limited to the exact facts of the Proposed Arrangement and can only be relied up on by the requesting Medical Center. Nevertheless, the factors that the OIG considered in making its favorable conclusion are instructive for other providers contemplating or structuring similar patient assistance programs. The following summarizes the significant features of the Proposed Arrangement and the OIG's

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identification and analysis of favorable factors.

Significant Features of the Proposed Arrangement. In its advisory opinion request, the Medical Center certified that the Proposed Arrangement would provide qualifying patients with 1) free or reduced-cost lodging for a single room at a modest (currently $70/night), privately-owned, hotel for one night before and up to two nights after treatment at a Medical Center hospital (*"Hospital"*); and 2) free or reduced-cost Hospital cafeteria meals, not to exceed a value of $15 per overnight stay. The Proposed Arrangement would only apply to patients (*"Eligible Patients"*) who:

1. reside 90 miles or more from the Hospital,
2. live in either a "medically underserved area" or "health professional shortage area," both as defined by Federal statute,
3. have a household income not exceeding 500% of the Federal poverty level, and
4. are either (a) required to be present for evaluation at the Hospital before 10am, or (b) have a follow-up appointment or procedure at the Hospital within 48 hours of on-site care.

Eligible Patients would be identified after scheduling for treatment at the Hospital, and Hospital staff would determine amount of assistance to be provided using a financial need-based sliding-scale established under Hospital-written financial assistance policies. The Proposed Arrangement would not limit the number of times an Eligible Patient could receive free or reduced-cost lodging and meals, would not consider a patient's insurance status in determining eligibility, would not be advertised to patients, and would not condition eligibility upon the receipt of any particular item or service. The Medical Center estimated that the Proposed Arrangement would apply to approximately 100 to 200 Eligible Patients annually. Additionally, the Medical Center certified that no remuneration would be provided by Medical Center or Hospital to any clinician to encourage him or her to refer Eligible Patients to the Hospital and that no costs of the Proposed Arrangement would be shifted to a federal health care program or be included in costs otherwise reported on a Hospital cost report or claim. Importantly, the Hospital indicated that it would audit and monitor the Proposed Arrangement under its compliance program.

OIG Identification and Analysis of Favorable Factors. The Opinion explains that the Proposed Arrangement implicates both the AKS and the Beneficiary Inducement CMP because the remuneration being provided to federal health program beneficiaries — in this case, the free or reduced-cost meals and lodging — "could induce a beneficiary to select the Hospital as his or her provider for federally reimbursable inpatient or outpatient services." Ultimately, the OIG concludes that the Proposed Arrangement would not constitute grounds for sanctions under the Beneficiary Inducements CMP because the remuneration contemplated under the Proposed Arrangement satisfied the two requirements of the Promotes Access to Care Exception — the free or reduced-cost meals and lodging: 1) promotes access to care and 2) poses a low risk to the Medicare and Medicaid programs and the beneficiaries of such programs.

In a two-part analysis, the OIG determined, first, that the Proposed Arrangement promotes a beneficiary's access to care by improving a beneficiary's ability to obtain items and services payable by Medicare and Medicaid. In this case, the OIG noted that the combination of free or reduced-cost lodging and meals served

to remove certain socioeconomic, geographic and economic barriers that could prevent Eligible Patients from getting necessary Hospital services and facilitated Eligible Patients attendance at treatment appointments to obtain medically necessary care. Notably, the Hospital operates a Level I trauma center and provides specialized services such as organ transplants and advanced outpatient oncology.

Second, the OIG concluded that the Proposed Arrangement posed a low risk of harm to the Medicare and Medicaid programs and beneficiaries because the Proposed Arrangement: 1) is unlikely to interfere with clinical decision-making, as patient eligibility is not dependent on the receipt of any particular service and clinicians are not compensated for referring Eligible Patients to the Hospital; 2) is unlikely to increase costs to the Medicare or Medicaid programs (e.g., overutilization or inappropriate utilization), as the Proposed Arrangement is not advertised, patient eligibility is only determined after treatment is scheduled, and the Medical Center certified it would not shift costs to the Federal health care programs or report associated costs on the Hospital's cost reports or claims; and 3) would not raise patient safety or quality-of-care concerns because rather than encouraging Eligible Patients to seek out unnecessary or poor care, it would remove obstacles preventing patients from obtaining necessary treatment.

Importantly, the OIG recognized that Beneficiary Inducement CMP exceptions do not apply to the AKS. However, in demonstrating the potentially broad reach of the Promotes Access to Care Exception, the OIG concluded that the Medical Center would not be subject to administrative sanctions under the AKS in connection with the Proposed Arrangement "for the same reasons" described in its analysis of the applicability of the Promotes Access to Care Exception. Any providers looking to structure similar patient assistance programs would be well-served in closely reviewing the Opinion, and incorporating as many of the favorable factors identified by the OIG into its program as possible.

Kansas Votes to Expand Medicaid, Embracing a Key Measure of the Affordable Care Act; Veto Possible

On Monday, a few short days after the failure of the Republican health care reform bill — the American Health Care Act (*"AHCA"*) — the Kansas Senate embraced a key measure of the Affordable Care Act (*"ACA"*) by voting to expand the state's Medicaid program to anyone earning less than 138% of the federal poverty level. A coalition of moderate Republicans and Democrats in the state Senate supported the measure, which passed by a vote of 25-13. The state House voted in support of the measure earlier this year. A study by the Kansas Health Institute projects that the expansion will extend eligibility to about 150,000 additional low-income people. Many expect that Kansas Governor Sam Brownback will veto the bill, as he has consistently signaled his opposition to the ACA and Medicaid expansion. While the state legislature could override a veto with a two-thirds majority in each chamber of the state legislature, because the bill was not initially approved by supermajorities in either chamber, such an override is unlikely.

If Kansas' Medicaid expansion is successful, it would become the 32nd state to adopt the ACA's Medicaid expansion. Whether other states will explore Medicaid expansion now that the ACA's federal funding of the expansion remains law, is yet to be seen. However, at least two state governors — Terry McAulifee of Virginia and Nathan Deal of Georgia — have signaled that possibility.

With AHCA Withdrawn, What's Next for Health Care Reform?

With last week's withdrawal of the American Health Care Act (*"AHCA"*), immediate health care reform efforts may now shift from legislative action to regulatory and executive action. As previously examined in our February 23 Health Care Regulatory and Legislative Update, the Department of Health and Human Services' (*"HHS"*) Centers for Medicare & Medicaid Services (*"CMS"*) has already issued a proposed rule aimed at stabilizing the health exchange markets while the future of the ACA was debated. Whether the administration will move forward with those stabilizing efforts in light of the AHCA's legislative failure is yet to be seen. Although President Trump told The Washington Post shortly after the AHCA's withdrawal that ""[t]he best thing politically is to let Obamacare explode", HHS recently updated its website to explain the regulatory changes it is making to overhaul the ACA, including changes to stabilize insurance markets: The webpage, dubbed "Providing Relief Right Now for Patients," states:

> "The Department of Health and Human Services (HHS) is committed to doing everything in our power to provide relief immediately. Within what the law allows, HHS is taking action to stabilize the individual and small group insurance markets (the markets most affected by the ACA) so that they work better for everyone. We are going through every page of regulations and guidance related to the Affordable Care Act to determine whether or not they work for patients and whether or not they are making our health care system better."

The website also highlights that HHS would like to partner with states to revamp the Medicaid program on a state-by-state basis. In a March 14, 2017 letter from HHS Secretary, Tom Price, and CMS Administrator, Seema Verma, the administrators encourage states to "come up with ideas of their own for the program" and lay out some of their Medicaid innovation suggestions for the states, including introducing health savings accounts and requiring small premiums or other contributions from patients in order to encourage personal responsibility.

Other key administrative actions that could have a significant impact on the stability of the ACA health insurance markets include (1) whether the administration will enforce the ACA's individual insurance mandate (e.g. — continue to collect penalties from those that do not obtain insurance as required by the law), and (2) whether the administration will encourage Republicans to drop the *House v. Price* lawsuit — the suit 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 (see our February 23 Health Care Regulatory and Legislative Update for more information on that status of this case). Failure to take either action before exchange insurers submit initial premiums for next year could result in further increased premiums or additional insurer withdrawals.

We will continue to monitor and report as the future of health care reform unfolds.