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Memorandum

Date: November 16, 2016

To: Health Care Clients & Friends

From: Holland & Knight Federal Health Team

Re: Healthcare Regulations and Other Guidance Pending under the Current Administration

As of November 16, 2016, there are 25 Department of Health and Human Services (DHHS) regulations under review at the Office of Information and Regulatory Affairs (OIRA). OIRA reviews hundreds of significant proposed and final rules from all federal agencies before they are published in the *Federal Register*. Of note, there are several additional DHHS regulations anticipated for release this year that are not yet under OIRA review or may not require OIRA review.

The fate of these regulations are uncertain as House Republicans sent a letter on November 15, 2016 to every government agency asking them to halt all rulemaking until President-elect Donald Trump takes office. To that end, the House of Representatives will vote later this week on a bill to prevent last-minute regulations, although the White House has promised to veto the bill.

If legislative efforts to curtail the release of pending regulations proves futile, an incoming Trump Administration may institute a moratorium on pending regulations through the use of an administrative memorandum. For example, in a memorandum dated January 20, 2001, Bush White House Chief of Staff Andrew Card directed all agencies to withdraw Clinton originated regulations sent to the *Federal Register* but not yet published. The Card memo also directed agency heads to "postpone the effective date of [recently issued but not yet effective] regulations for 60 days to ensure that the President's appointees have the opportunity to review any new or pending regulations."

Despite a delay in the effective date, once a final regulation has been published in the *Federal Register*, the only unilateral way an administration can revise it is through new rulemaking under the *Administrative Procedure Act*. As such, the health-care industry is not expecting the Obama Administration to propose any new major rules in its final months, but it is expected that DHHS will release a number of final rules/guidances with a potentially far-reaching impact.

Highly Anticipated DHHS Pending Regulations Include:

340B Drug Discount Program Mega-Guidance: On August 28, 2015, the Health Resources and Services Administration (HRSA), the agency within HHS that oversees the 340B Drug Discount Program, released its proposed "mega" guidance regarding pharmaceutical manufacturer and covered entity participation in the 340B Drug Discount Program. The proposed guidance addressed a broad range of topics within the 340B Program, including the definition of patient, contract pharmacy compliance requirements,

hospital eligibility criteria and eligibility of off-site outpatient locations. Final guidance on the 340B Drug Discount Program is under review at OIRA as of September 1, 2016. The final guidance is anticipated for release in December 2016.

Pass-Through Payments in Medicaid Managed Care Delivery Systems: On April 25, 2016, CMS released a Final Rule that entailed a massive update to managed care in Medicaid and the Children's Health Insurance Program (CHIP). In the Medicaid managed care regulations, CMS acknowledged that despite its policy that states should not direct managed care plans' expenditures under the contract, a number of states have integrated some form of additional payment to providers, defined in the final rule as pass-through payments. Since publication of the Medicaid managed care regulations, CMS has received inquiries about states' ability to integrate new or increased pass-through payments into Medicaid managed care contracts. Accordingly, CMS will address this policy in future rulemaking, linking pass-through payments through the transition period to amounts in place at the time the Medicaid managed care rule was effective on July 5, 2016. The regulation addressing pass-through payments is currently under review at OIRA as of October 18, 2016.

Advancing Care Coordination Through Episode Payment Models: On July 25, 2016, CMS released a proposed rule advancing three new Part A and B mandatory bundled payment models –which it calls episode payment models (EMPS)--for acute myocardial infarction (AMI, or heart attack) treated with or without percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG) and surgical hip/femur fracture treatment (SHFFT) episodes. Comments were due October 3, 2016. The program, as proposed, is slated to begin July 1, 2017. As such, a Final Rule is anticipated for release before the end of the year. Currently, the final regulation is not under review at OIRA.

Medicare Part B Demonstration: On March 8, 2016 CMS released a proposed rule that would dramatically change the way Medicare pays for Part D drugs. This change would affect a broad definition of drugs, including Part B drugs, biologics, and biosimilars. The proposed rule is a two-phase model that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. In the coming months, CMS may publish a final rule on the pilot program. Many oncology trade associations and pharmaceutical companies oppose the proposed rule, and both Republican and Democratic members of Congress have raised concerns with the CMS proposal. Currently, the final regulation is not under review at OIRA.

2018 Notice of Benefit and Payment Parameters: On August 29, 2016, CMS released its proposed 2018 Notice of Benefit and Payment Parameters. The "payment notice," as it is called, is an annual CMS omnibus rule that pulls together in one place all the major changes the agency intends to implement for the next plan year for the marketplaces (in particular the federally facilitated exchange (FFE) and SHOP marketplaces), the premium stabilization programs, and the health insurance market reforms generally. The proposed notice followed announcements by several national insurers that they would exit the health insurance exchanges in a number of states. A final regulation is anticipated but is not currently under review at OIRA.

Anti-Kickback Statute Safe Harbors, Civil Monetary Penalty Rules Regarding Gainsharing: On October 3, 2014, the Office of Inspector General (OIG) of DHHS issued proposed regulations regarding exceptions to the Anti-Kickback Statute (AKS), and the Civil Monetary Penalty (CMP) provisions of the Social Security Act. A Final Rule is under review at OIRA as of August 16, 2016. The expected Final Rule would revise anti-kickback statute safe harbors as well as expand the use of gainsharing arrangements.

The gainsharing CMP has already been revised under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Prior to MACRA, hospitals were prohibited from paying cost-savings bonuses to doctors, because presumably that could induce a reduction or restriction of services to patients, even if the services were medically unnecessary. MACRA revised the wording of the gainsharing CMP to prohibit only payments that triggered reduction or restriction of medically necessary services. A final regulation is currently under review at OIRA as of August 16, 2016.

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