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Memorandum

Date: November 11, 2016

To: Health Care Clients & Friends

From: Holland & Knight Federal Health Team

Re: Post-Election Health Care Outlook

The election of 2016 is undoubtedly a game-changer and is likely to produce a reset in the legislative and regulatory arena for the health care sector. This memorandum is intended to provide a high-level outlook for our collective health care clients.

After a historic and unexpected victory, the Trump's transition team is under pressure to quickly finalize the President-elect's policy agenda for the first 100 days and narrow down the list of candidates for top administration jobs. Presidential transition teams develop policy plans and come up with a list of incoming president appoints, including White House jobs, cabinet secretaries, and lower level positions. Holland & Knight is participating in many of these discussions.

Our Federal Health Team, and our entire firm-wide Health Care Industry Team, are ready to assist our clients identifying opportunities and threats, and to proactively assist you in navigating the next tumultuous several months in the regulatory and legislative realms. Please find further information on our new [Presidential Transition Analysis Center](#).

I. OUTLOOK FOR LAME-DUCK:

The Obama administration and current 114th Congress still have items to resolve before the end of the year. So far, the emerging agenda for the lame-duck congressional session seems relatively limited to must-pass items.

Appropriations: Few on Capitol Hill want to see a government shutdown just ahead of the holiday season, yet it is unclear how FY'17 spending will be finally resolved. Senate Majority Leader Mitch McConnell (R-KY) and the Appropriations Committees have expressed a desire to finalize the appropriations bills into an omnibus bill and enact it in December. The bill is largely already assembled among the Appropriations Committees, but would require either the assent of House conservatives, or sufficient Democratic votes to pass in the House. Alternatively, pressure is already mounting among conservatives to delay an omnibus bill now and await incoming President Trump to finish out the FY'17 appropriations legislation rather than negotiate with an outgoing Obama Administration. Thus, it is possible that the Congress could move to enact a short-or long-term Continuing Resolution (CR) at current funding levels delaying final resolution, most likely until March or April of 2017.

Remaining Health Care Bills:

- ***21st Century Cures:*** Much of the health care legislation left on the table when Congress left town, such as the 21st Century Cures Act, has been hanging in the balance for nearly all of 2016. House and Senate negotiators have been working for months to resolve differences between the House and Senate versions of this legislation. The main sticking point has been funding for NIH and FDA initiatives. Prior to the election, the two sides were far apart and an agreement seemed unlikely. Since election day, Senate Republican Leader McConnell (R-KY) has said that enacting the Cures Act during the lame duck congressional session is a priority. There is no word yet on whether Democrats and the Obama Administration agree or what provisions from the original bill would be included.
- ***Site-Neutral:*** A key priority for the hospital community remains legislative changes to the site neutral provision enacted a year ago to grandfather hospital clinics under development prior to the date of enactment in November of 2015. Absent any legislative changes, reduced reimbursement begins on January 1, 2017; thus, some legislative relief for certain hospitals continues to be a major push for the hospital industry.

Congressional Leadership: Aside from legislative work, the lame-duck will also see the House and Senate elect new leaders for the next Congress. Senate Majority Leader Mitch McConnell (R-KY) is expected to remain the GOP leader. Democrats are expected to elect Senator Charles Schumer (D-NY) as the new Minority Leader with retirement of Senator Harry Reid (D-NV) at the end of this Congress. In the House of Representatives, Speaker Paul Ryan (R-WI) is likely to be re-elected by his caucus, despite some concerns expressed by the House Freedom Caucus. House Minority Leader Nancy Pelosi (D-CA) is expected to be re-elected unless she decides to vacate the post.

DHHS Secretary: President-elect Trump will shortly begin to put together his Cabinet. Although the situation is quite fluid, Dr. Ben Carson, former GOP presidential candidate, has begun to emerge as a possible candidate for DHHS Secretary.

II. OUTLOOK FOR 2017:

Upon his swearing in on January 20, 2017, President Trump and the 115th Congress will quickly face challenging questions on a number of critical health care issues.

II.A. PARTIAL REPEAL AND REPLACE OF THE ACA:

President-elect Trump and the Republican leadership in Congress have long pledged to repeal the Patient Protection and Affordable Care Act (ACA). Following the election, both Senate Majority Leader McConnell (R-KY) and House Speaker Ryan (R-WI) reaffirmed their intention to move swiftly to repeal the ACA, but also to ensure an appropriate transition. Over the past several years, a number of proposals have been advanced for repealing the ACA, which became law in March 2010. It is important to understand the key differences between past GOP attempts to repeal the ACA and future GOP attempts to repeal the ACA.

Repeal: It is unlikely that the ACA will be fully repealed exactly as it was enacted for several reasons. While the Senate remains in Republican control, with an expected 52 votes, they do not have a filibuster-proof majority. Thus, it's unlikely they will be able to fully repeal the ACA as it was enacted as doing so would require 60 votes. Rather, Republican leadership is expected to pursue partial repeal of the ACA

through the budget reconciliation process, which allows for expedited consideration of certain tax, spending, and debt limit legislation to be passed by a simple majority, without being subject to a filibuster. Some provisions that do not have a budgetary impact may be trickier for the Republicans to repeal or amend as Senate rules prohibit inclusion of provisions that do not have a budgetary impact in budget reconciliation legislation. Democratic opposition to any effort to repeal is, not surprisingly, mounting in earnest.

Tax Issues: A number of provisions in the ACA and that Republicans want to replace it with implicate the tax code, thus complicating the procedural process in which repeal and replace will be considered. We anticipate that the Republican led House and Senate will agree upon a Budget Resolution (budget blueprint) in the early spring, which will serve as the legislative vehicle for repealing and replacing much of the ACA, including a variety of tax provisions. These health and tax related issues could also be addressed as part of a larger tax reform effort, but they are foundational to the Republican “replace” proposals and thus the Republicans must work through their substantive and political approach on the intersection of both tax and ACA reforms.

Retain: While not part of the political rhetoric, it is also important to recognize that there are a number of provisions that Republicans support, such as the shift from fee-for-service reimbursement to value based purchasing for providers and a number of insurance protections for consumers. For example, certain provisions of the ACA, such as denying individuals health care based on preexisting conditions and allowing children to stay on their parent’s plan until the age of 26, are supported by Republican leadership. In addition, it is unclear what the Republican appetite will be for repealing certain coverage provisions without a period of transition and a solid replacement proposal. Further, prior “replace” discussion drafts from leading Senate Republicans have considered maintaining the major Medicare reimbursement changes in the ACA, including cuts in reimbursement to providers and quality requirements. Note that the ACA also contains other provisions such as a pathway for a biological biosimilar products that we expect to be retained.

Replace: There is no perfect agreement yet between the House, Senate and the incoming Trump Administration on exactly what the “replace” legislation will embody. However, there are a variety of themes demonstrating consistency among them that are likely to be major focal points of any Republican plan.

- **Insurance Coverage:** We anticipate Republican sensitivity to the many millions of Americans receiving coverage under the ACA to retain some kind of insurance plan for their families, including those who are receiving subsidized coverage through the Health Insurance Marketplaces. Republicans will have to find the balance in redesigning and providing access to coverage for those who have come to depend upon it, particularly those with chronic and expensive conditions. Some key themes emanating from Republican “replace” proposals include enhancing transparency and portability of coverage, redesigning subsidization of insurance for low-income individuals, providing greater choice and flexibility in coverage and benefit design, empowering consumer responsibility for their health care decisions, and enhancing competition among insurers and providers to drive down costs. Republicans have indicated a desire to preserve and strengthen employer sponsored health insurance, and to enable purchase of insurance across state lines.
- **Medicaid:** Republicans are likely to consider major structural changes to Medicaid including potentially providing a block grant to states or a per capita allotment which would be set by capping the amount of federal matching per beneficiary in four categories: aged, blind and disabled, children, and adults. They are expected to consider revamping 1115 State waivers, and providing substantially greater flexibility to States in running their Medicaid programs. How to address the disparity between those states that have already expanded under the ACA and those that have not,

as well as the disparity within matching rates for the prior Medicaid population, the expanded population and CHIP, are expected to be discussed as well.

- **Medicare:** It is unclear whether there is alignment on major structural reforms to Medicare, although leading Republicans, including President-elect Trump, have indicated a desire to “protect” Medicare. It is possible that premium supports in the form of a defined contribution may be considered. The combination of Parts A and B has also been proposed to simplify and streamline the programs, including cost-sharing requirements for beneficiaries.
- **Cost:** Amending the ACA in whatever form will have major cost implications – potentially adding to or reducing federal expenditures. Several tax provisions in the law, such as the medical device tax (currently suspended for 2 years) and the “Cadillac tax” on high-value plans, raise billions that are utilized for coverage and other expenditures under the ACA. Republicans will be seeking to reduce and not add to federal expenditures, but proposed legislative changes are subject to Congressional Budget Office (CBO) scoring, and ACA cost-savings are incorporated into the baseline used by CBO, making changes potentially costly in the eyes of CBO.
- **Other ACA Replace Themes:** Other key themes include spurring innovation, medical liability, reducing regulatory burden on states, insurers, pharmaceutical manufacturers and providers, and addressing medical liability.

Open Questions: There are a myriad of open questions in terms of repeal and replace, but several worthy of special attention:

- **Center for Medicare and Medicaid Innovation (CMMI):** What happens to CMMI? The Republicans have long criticized the Medicare's Innovation Center for receiving an extraordinary amount of statutory authority and power under the ACA; the House Republican “A Better Way” plan proposes to defund it in 2020. 176 Members of Congress asked CMS to commit to seeking congressional approval if expansion of demonstrations require changes to the underlying statute. Accordingly, it is likely the GOP will look to repeal or at least limit the scope of CMMI. However, it does provide the Administration with tools to implement payment changes outside of the legislative process, giving President-elect Trump's team a possible reason to retain it.
- **MACRA:** What happens to the *Medicare Access and CHIP Reauthorization Act* (MACRA)? The one policy area that has received broad bipartisan support in Congress is payment reform, which incentivizes providers to take part in value-based payment models. MACRA passed with huge majorities in both the House and Senate. Because MACRA puts long-term pressure on physicians to adopt Alternative Payment Models such as ACOs and bundled payments, any action to roll back those programs (repealing ACA wholesale or defunding CMMI, for example) could serve to undermine MACRA's effectiveness.
- **Medicare Advantage:** Will Medicare Advantage (MA) become the dominant form of Medicare coverage? Both MA enrollment and provider interest in offering MA plans have been on the rise, and a Republican-controlled government could expedite an even quicker shift given their long-standing support for MA. While it is not likely that MA (or, for that matter, any other privatized Medicare model) will fully supplant traditional Medicare in the immediate future, providers would be wise to craft strategies that address both the MA and traditional Medicare segments in complementary ways.

It is important to recognize the investment of Democrats in preserving the coverage of millions of Americans and the legacy of the ACA they worked so diligently to enact and implement. Advocacy groups, such as Families USA, and many others are already pledging a major battle to preserve the ACA. We expect it will take a number of months to consider such major legislation to repeal and replace it, and that a transition period will be essential. However, unlike prior attempts to eliminate or amend the ACA, there will now be a Republican President committed to sign such a repeal and replace bill. We've provided several hyperlinks below that are worth reviewing to get a better sense of the policies the Republicans may promote and coalesce around, as well as the issues they'll want to raise in the process.

- [President-elect Trump Healthcare priorities](#)
- [Speaker Paul Ryan's healthcare proposal](#)
- [Republican Senators Richard Burr, Tom Coburn, and Orrin Hatch released a blueprint for repealing and replacing ACA](#)

II.B. OTHER HEALTH CARE ISSUES:

There are a number of major must-address health care issues that were delayed until after the election and some provisions expiring as early as September 30, 2017 that will need to be addressed next year. Several of these issues may be wrapped up into a repeal and replace effort, or they could be addressed independently, especially given the short time frame in which they must be considered.

Children's Health Insurance Program (CHIP): Funding will expire at the end of September 2017, making a reauthorization bill a must-pass agenda item for the next Congress. The program's legislative authority expires in 2019, as will requirements that prevent states from making it harder for people to enroll in the program. The levels at which it is funded may also be contentious. Some Republicans would prefer a lower spending level, but states that rely on the funds and child advocacy organizations will push to keep current spending levels. Some Republican proposals to replace the ACA have included major changes to CHIP; it remains unclear whether it will be wrapped into the larger discussion, receive a short-term extension while the larger dialogue is continuing, or receive a long-term extension without major alterations.

Medicaid DSH Cliff: In the absence of additional Congressional action, disproportionate share hospitals (DSH) serving high numbers of low-income and vulnerable citizens face a \$2 billion cut under the ACA beginning October 1, 2017, climbing \$1 billion per year to \$8 billion in 2024. There will be a major initiative from the hospital community to push back or eliminate these enormous reductions. Republican proposals have considered changes to Medicaid DSH, as well as Medicare DSH; whether these DSH issues are considered part of a larger reform effort is also unclear. Given the connection between coverage and uncompensated care, including charity care and losses on Medicaid, we anticipate a robust discussion about safety-net financing.

Medicare Extenders: A host of other key funding "extenders" that are set to expire next year and in 2018 that also hang in the balance. The extenders set to expire are as follows:

- Medicare Extenders: Medicare Work Geographic Adjustment (GPCI) Floor (Jan. 1, 2018);
- Extension of Therapy Cap Exceptions Process (Jan. 1, 2018);
- Medicare Ambulance Add-on Payments – Extends the add-on payment for ground ambulance services, including in super rural areas (Jan. 1, 2018);
- Extension of Low-Volume Hospital Adjustment (Oct. 1, 2017);
- Extension of Medicare Dependent Hospitals program (Oct. 1, 2017);

- Medicare Advantage Special Needs Plans (extends authority for SNPs) (Dec. 31, 2018);
- Transition and Extension of Medicare Cost Contract Plans;
- National Quality Forum and Pre-Rulemaking Process Funding (Oct. 1, 2017);
- Outreach and Assistance Funding for Low-Income Programs (Oct. 1, 2017);
- Medicare Home Health Rural 3% Add-On (Jan. 1, 2018);

II.C. EXECUTIVE ACTIONS:

President-elect Trump and Senate Majority Leader McConnell (R-KY) have already indicated that rescinding a number of President Obama's Executive Orders will be a high priority. Even though Republicans have been critical of Obama's use of Executive Orders, President-elect Trump may use them as a mechanism to cause immediate change. Such executive orders may impact cost-sharing subsidies to insurance companies, risk corridor payments, and enforcement of the individual mandate. For a listing of executive actions that the House Republicans believe were unlawful please see page 11 of "[A Better Way.](#)"

III. ACA REFORM IMPACT ON HEALTH CARE SEGMENTS:

III.A. PATIENTS:

President-elect Donald Trump's most updated health care proposals largely encompass broad sweeping statements on major health care issues without much detail. While a greater level of specificity is provided by Congressional Republican replace proposals, ambiguity exists around a number of issues affecting patient access to care. These issues include the cost of coverage for families and patients with expensive and complex conditions, and whether require consumer protections will remain. Additional concerns have been raised by patients about narrow networks and access to the doctor and hospital of their choosing under the ACA.

In a variety of proposals, many Republicans have offered different ways to provide access to health insurance for those not eligible for employer-sponsored insurance or who aren't otherwise covered by another government insurance program, such as Medicare. The proposals on the table would make substantial alterations to the structure of ACA coverage, including the potential removal of essential health benefits as required under the ACA. Many Republicans have proposed allowing patients to select plans from a more robust offering among insurers that are more narrowly tailored for their needs so that individuals and taxpayers aren't paying for coverage that isn't needed and so that patients select the doctor or hospital of their choice.

Despite many substantial policy differences between Republicans and Democrats, there is some consistency between the goals of the ACA and proposals for its potential replacement centering around patients that should not be overlooked -- to provide access to high quality health care and appropriate benefit coverage and utilization, reduce health care costs, ensure affordability for families, and protect the safety-net for providers serving vulnerable and low-income populations.

Preceding enactment of the ACA, the legislative debate was dominated by *whether* to provide coverage to uninsured individuals, and if so, what kind of coverage should be provided, and how to pay for it. Early repeal proposals focused on repeal first and replace later. After several years of millions of Americans receiving coverage under the ACA, the conversation surrounding repeal and replace appears to have shifted from *whether* to facilitate or subsidize coverage, to a debate about *how* to provide access to affordable coverage and what types of structural reforms would enhance quality, access and lower health care costs.

III.B. PROVIDERS:

Many segments of the health care provider community supported the ACA. They will want to ensure that any potential replacement does not reduce insurance coverage for their patients or impede access to their services, and does not result in dramatically reduced reimbursement from all payers. Consideration of major repeal or changes to ACA is both a potential threat and opportunity for providers.

President-elect Trump and other Republicans have proposed significant Medicaid reforms by limiting the growth of federal funding for Medicaid while shifting greater control over eligibility and benefits to states. Such reforms—whether in the form of per capita allotments or block grants—might lead states to alter some combination of eligibility, benefits, and payment rates. Greater flexibility could also spur innovation and structural changes on a state-by-state basis. For providers, such major changes may impact revenue, volume, and service offerings.

There is no proposed replacement for the continuation of value-based payment models for a variety of providers subject to them, under which they are rewarded or penalized in their Medicare reimbursements based on actual performance on a wide range of quality and outcome metrics—such as ACOs and bundled payments. Should efforts be advanced to temper value-based payment models, there may be a significant impact on the implementation of MACRA in particular. However, many providers and other stakeholders might well voice a preference for value-based models as a cost control strategy over fee-for-service rate cuts. That viewpoint could encourage the new Congress and Administration to continue to support risk-based payment and pay-for-performance models.

Some proposals coming from the Republicans, including around medical liability and repeal of the Independent Payment Advisory Board (IPAB), will be welcomed by the provider community. They may also seek and receive regulatory relief from the burdensome red tape governing their provision of health care services and legal impediments to clinical integration.

III.C. INSURERS:

The ACA contained a number of provisions that changed the product insurers could offer. For example, plans generally cannot impose lifetime or annual limits on essential health benefits and have to provide coverage for certain preventative health care service, e.g. contraception, without cost-sharing to enrollees. Importantly, the ACA also limited the factors that can be considered when calculating health insurance premiums. It is likely that Republicans will try and repeal some of these provisions and allow states to resume their traditional role in regulating insurers. As discussed above, some of the more popular provisions such as the prohibition to deny coverage to individuals based on preexisting conditions could be retained. Key to both the President-elect Trump platform and that of Republican leadership on Capitol Hill is to allow insurers to sell insurance across state lines in an effort to spur competition and drive premiums down. It is likely that there will be a lot of changes and impact on insurers.

III.D. MEDICAL DEVICES:

If there was any doubt about the resuscitation of the 2.3 percent excise tax on medical devices, then those doubts were most certainly extinguished with the election of Donald Trump and a House and Senate controlled by the Republicans. The medical device tax was a key financing feature of the ACA, and was always opposed by the medical device industry. The tax was delayed for two years in December 2015, and is scheduled to be reinstated next year. We can expect the new Administration and the Republican Congress to press for its elimination in perpetuity.

The FDA has also been wrestling for years with what is considered off-label promotion of medical devices (as well as drugs). For years, the agency has tried to control what manufacturers can and cannot say about their products. Ultimately, the First Amendment has interrupted the FDA's effort to control these communications. And in response to litigation successfully brought by industry, the FDA has continued to try to limit what manufacturers say about their products. Just this week, on the day after the election, the FDA held a two-day forum on off-label promotion in an effort to re-engage all stakeholders. FDA Commissioner Califf opened the meeting by acknowledging the uncertainty that laid ahead. Who will be running the FDA remains very much an open question this soon after the election. But suffice it to say that a Trump Administration will likely want to change the FDA's leadership. Whether this change is limited to the Commissioner's slot or seeps down to CDRH (and other Center Directors) remains to be seen. Regardless, we anticipate the agency being more friendly to business. We would question, therefore, a Trump Administration FDA's appetite for limiting off-label promotion beyond the restrictions currently imposed by case law.

IV. PHARMACEUTICALS/BIOTECHNOLOGY LANDSCAPE:

Prescription Drug User Fee Act and Other User Fee Legislation: In 1992 Congress enacted the prescription drug user fee system. Under the program, the pharmaceutical industry and the Food and Drug Administration (FDA) negotiate an agreement which sets a certain amount that pharmaceutical companies pay each year, known as a user fee, to fund certain initiatives at the agency. That agreement typically is reauthorized every five years and has grown to include the medical device and generic drug industries, among others. User fees now account for almost half of the FDA's total budget. Next year, Congress will be tasked with reauthorizing the agreements before the current law expires at the end of September 2017.

User fee agreements between FDA and regulated industry have been reached regarding prescription drugs/biologicals, generic drugs, biosimilars, and medical devices. Legislation to implement these agreements will be debated and enacted during the next Congress. This legislation will become a vehicle for any changes to the *Food, Drug and Cosmetic Act* relating to review and approval of FDA-regulated products. That could include new pathways or modifications of existing regulatory pathways for advanced therapy drugs (such as cell and gene therapies) as well as cosmetics and non-prescription (Over-the-Counter or "OTC") drugs.

President-elect Trump has said that he will pursue "[r]eforms [that] will also include cutting the red tape at the FDA: there are over 4,000 drugs awaiting approval, and we especially want to speed the approval of life-saving medications." At the very least, President-elect Trump will support "Right to Try Laws" that attempt to provide access to unapproved drugs. Vice President-elect Mike Pence supports a Right to Try law in Indiana as governor and advocated for it during the campaign. FDA's views on these matters will likely be influenced by the new FDA Commissioner.

Drug Pricing: During the campaign, President-elect Trump expressed concerns about high drug prices and pledged to address these issues if elected. He has discussed two ways to lower prices:

- ***Importation:*** President-elect Trump proposes removing barriers to allow easier entry into the U.S. for drugs from overseas. Details are not clear and historically, FDA has resisted expanded importation, saying it cannot certify the safety of the products.
- ***Medicare Negotiations with Pharmaceutical Companies:*** President-elect Trump has proposed giving Medicare the authority to negotiate drug prices with companies. Again, details on how this would work are unknown, as Medicare currently deals with private insurers which design and sell Medicare Part D

plans and already negotiate with manufacturers. Whether this would in some way apply to drugs paid under Part B is unclear.

With many congressional offices also clamoring for action on drug prices – especially with the upcoming debates about how to improve the regulatory pathway for industry – it is likely that new Congress and the Trump Administration will push some form of legislation to address drug prices. As part of the drug pricing discussion, we also expect a potential dialogue around changes to the 340B drug discount program.

In addition, as noted, it is possible that as part of efforts to repeal the ACA, the Trump Administration and Congress will eliminate the CMS Medical Innovation Center. As this was the focal point of CMS efforts to develop new payment models for medical products, the details of future Medicare payment reforms affecting new drugs and biologics are in question.

Medical Research: President-elect Trump has said very little about biomedical research or NIH funding, although in one interview, he stated he hears “so much about the NIH, and it’s terrible.” The futures of the Cancer Moonshot program and the Precision Medicine Initiative are unclear though both have bi-partisan congressional support. There is speculation Vice President-elect Pence may seek new limits on federal funding for embryonic stem-cell research. Despite this, we expect support for general NIH and biomedical research funding in the 115th Congress.

V. OTHER FDA REGULATED INDUSTRY LANDSCAPE:

FDA Regulatory Process: Congressional discussions are already underway regarding possible changes to the regulatory pathway to market for cosmetic products as well as OTC drugs, including the establishment of new user fee programs. It is likely that the FDA user fee legislation noted above will also contain reforms to the review and approval process for these products.

VI. CONCLUSION:

Major changes to health care sector are going to be considered and debated in the coming months. Given Republican control of the Congress and Presidency, we anticipate that some changes will be enacted affecting patients and major segments of the health care industry. Our team of lawyers and professionals at Holland & Knight look forward to working with our valued clients in navigating this period of uncertainty and helping you to identify, confront and mitigate potential threats, as well as to leverage potential opportunities.

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