WASHINGTON STRATEGIC CONSULTING

MEMORANDUM

TO: WSC Clients

FROM: Kyle Mulroy

DATE: June 2, 2016

RE: 2016 Mid-Year Federal Health Policy Report

INTRODUCTION

Congress will return from its Memorial Day break with less than four working weeks until they leave Washington again on July 17th for an extended summer recess designed to accommodate the presidential nominating conventions.

Leaders in both chambers will remain focused in the weeks ahead on upholding their pledge to pass all 12 annual appropriations bills before the end of the fiscal year. The federal budget process is moving along erratically thanks to partisan fighting between and among the parties. None of the annual spending bills cleared either chamber by the Memorial Day recess making it appear inevitable that a continuing resolution to fund the government beyond the September 30th end of the current fiscal year will be necessary.

The appropriations process will continue to dominate the legislative calendar but will be further slowed by the need to divert floor time to other priorities. Congress is expected to spend its time between now and the summer break on a series of non-appropriations bills, including the annual defense authorization bill, reauthorization of the FAA, Puerto Rico's debt crisis, regulation of toxic chemicals and several high-profile health measures.

Provided below is a brief summary of five health care bills that are under active consideration in Congress and likely to see further action in the weeks and months ahead.

Beyond legislative activity, federal agencies and departments are issuing consequential health-related rules and regulations, as well as developing new innovation models at a fast pace in the last year of this administration. A brief summary of agency developments of particular importance to health care providers is also provided below.

FIVE HEALTH CARE BILLS ON THE MOVE

MEDICARE HOSPITAL PAYMENT REFORM

On May 18th, the House Ways & Means Committee approved the Helping Hospitals Improve Patient Care Act of 2016 (H.R. 5273). The bill provides a very narrow exception to the recently established ban on new off-campus hospital outpatient departments for certain entities that were "mid-build" when the ban was created. The legislation also adds a socio-economic adjustment to the readmissions penalty program, studies differences in surgical codes between outpatient and inpatient settings and implements a small document and coding adjustment for FY 2018.

Future action on H.R. 5273 and possibly other hospital payment issues will likely occur as part of negotiations over an end-of-the-year legislative package during a post-election, lame-duck session of Congress. The Senate has not yet indicated its intentions on the issues included in H.R. 5273 and other payment issues of importance to the provider industry.

OPIOIDS

A House-Senate conference committee is working to reconcile competing versions of the Comprehensive Addiction and Recovery Act that passed both the House and Senate the week of May 9th. The legislation would create or expand federal programs to help states and local communities address the opioid epidemic. Neither House nor Senate version includes funding for the programs but more than $100 million is expected to be made available separately through the appropriations process.

ZIKA

Debate on the president's funding request to combat the Zika virus has dragged on for nearly four months. On May 16th, the House passed its FY 2017 military construction bill with $622 million for Zika. The Senate left Washington for the Memorial Day recess without giving final approval to its version of the bill that includes $1.1 billion. The Senate is expected to approve its bill and send it to conference with the House when they are back in session the week of June 6th. The final number is likely to be higher than the House amount but still less than the president's $1.9 billion request.

21ST CENTURY CURES

On April 6th, the Senate HELP Committee passed a 19-bill package of medical innovation reforms designed to accelerate medical research and streamline the federal approval processes for new drugs and medical devices. The package represents the Senate companion to H.R. 6, the 21st Century Cures Act, which passed the House last July. Senate leaders hope for floor approval before the summer recess so that a conference with the House can be completed and final approval given by the end of the year. Whether to include mandatory funding for the NIH, and if that funding should be offset by reductions elsewhere, is the main sticking point.

MENTAL HEALTH

The House Energy & Commerce Health Subcommittee approved H.R. 2646, the Helping Families in Mental Health Crisis Act last November. The bill's sponsor, Rep. Tim Murphy (R-PA), has been working to revise the legislation to address concerns by Democrats surrounding the loosening of patient confidentiality. A full committee markup is possible in June. The revised bill may include a scaled-down revision of the IMD exclusion policy.

The Senate HELP Committee approved a companion bill on March 16th. Senate leaders have indicated that the bill may be given floor consideration prior to the summer recess but they are wary, particularly given the coming elections, of politically controversial amendments that may be offered by both sides dealing with the gun debate.

REGS, RULES & DEMOS

OFF-CAMPUS HOSPITAL HOPDS

CMS is expected to detail its regulations for implementing Section 603 of the Bipartisan Budget Act of 2015 when the agency releases its FY 2017 outpatient prospective payment system proposed rule in July. Section 603 prohibits hospitals from creating new off-campus outpatient departments that are paid under the outpatient PPS. Departments that were operational at the time that the ban was made law (Nov 2, 2015) are exempt.

In May, 51 Senators and 235 Representatives wrote to CMS urging the agency to issue regulations that provide flexibility and not trigger the exclusion of existing and approved outpatient departments should those departments make future alterations in ownership, location, add additional services or make other changes that are standard and routine.

FY 2017 INPATIENT PROSPECTIVE PAYMENT SYSTEM PROPOSED RULE

On April 19th, CMS released its FY17 IPPS proposed rule and will accept comments through June 17th. The rule proposes to reverse a 0.2 percent cut stemming from the "two-midnight" policy by adjusting payments in 2017. The rule also includes: a one-year extension of the imputed wage index floor policy for all urban states, an adjusted net market basket adjustment of 0.85 percent, and a 1.5% documentation and coding cut (the doc & coding cut all but negates the gains from the two midnight cut reversal).

FY 2017 LONG TERM CARE HOSPITAL PAYMENT SYSTEM PROPOSED RULE

CMS released its FY17 LTCH proposed rule on April 18th. The rule continues to implement two different types of payment rates based on patients that meet certain clinical criteria. The traditional PPS payments are slated for a 6.9 percent reduction while cases that qualify for the alternative rate would receive a 0.3 percent increase. Comments are due by June 17th.

MEDICARE PHYSICIAN PAYMENT SYSTEM RULE

On April 27th, CMS released its proposed rule to implement the new physician payment system created by last year's the Medicare Access & CHIP Reauthorization Act (MACRA) also referred to as the "SGR doc fix". MACRA creates two payment options under a new Quality Payment Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APM). Performance measurements begin in 2017 with payment changes in 2019. CMS is accepting comments through June 27th.

OTHER PROVIDER PAYMENT RULES

On April 21st, CMS released three FY 2017 payment rules for inpatient rehabilitation, skilled nursing, and hospice care. Overall updates for FY17 would be: 1.6 percent for rehab, 2.1 percent for SNF, and 2.0 percent for hospice. Comments will be accepted on all three rules until June 20th.

HOSPITAL COMPARE STAR RATINGS

CMS announced on April 20th that the public release of its new five-star rating system for hospital quality originally scheduled for April 21st would be delayed until at least July. The delay followed complaints detailed in letters signed by hundreds of lawmakers to CMS in which they argued that faulty methodology would result in many hospitals, particularly safety-net institutions, receiving unfairly low scores despite high ratings from other prominent quality reports.

340B DRUG PRICING PROGRAM MEGA-GUIDANCE

Last August, the Health Resources & Services Administration (HRSA) released its 340B Drug Pricing Program Omnibus Guidelines. Commonly referred to as "mega-guidance", the proposed guidelines would alter numerous components of the program, including eligible patient definitions, eligible providers and enhanced "program integrity" measures.

HRSA initially indicated that the final mega-guidance would be released in September 2016, but on May 18th the agency indicated that the release will probably occur in December. In addition, HRSA has delayed the release of a final rule addressing 340B civil monetary penalties for manufacturers and 340B ceiling prices, and a proposed rule implementing a binding administrative dispute resolution process.

DOL OVERTIME RULE

On May 23rd, the U.S. Department of Labor issued a final policy that expands overtime payment eligibility under the Fair Labor Standards Act. The new policy increases the salary threshold determining guaranteed time and a half pay from $23,660 to $47,476 for a full-year worker. It also raises the level for highly compensated employees to be ineligible for overtime from $100,000 to $134,004 per year. The policy is effective December 1, 2016 although health providers that are primarily Medicaid-funded are exempt until March 2019.

MEDICAID MANAGED CARE OVERHAUL RULE

On April 25th, CMS issued a final rule to restructure Medicaid managed care requirements. The rule addresses numerous topics including network adequacy, quality of care standards, and plans' medical loss ratio. The rule also loosens the IMD exclusion by allowing states to make a capitation payment for enrollees with a short-term stay (no more than 15 days) in an IMD.

HEALTH CARE NONDISCRIMINATION RULE

As required by the ACA, on May 13th HHS released a final rule entitled Nondiscrimination in Health Programs and Activities. The rule prohibits discrimination in health care on the basis of race, color, national origin, age, disability and sex, including pregnancy and gender stereotyping. It also enhances language help for those with minimal English proficiency. The rule is effective July 18, 2016.

WORKPLACE WELLNESS PROGRAM RULE

On May 16th, the U.S. Equal Employment Opportunity Commission issued regulations clarifying the application of federal anti-discrimination laws in workplace wellness programs. Under the ACA, the incentive (or penalty) for participating (or not participating) in a wellness program typically may not exceed 30 percent of a group health plan. The rule was developed in response to criticisms that the financial incentives were too high and forced employees to provide medical information. Under the new rule, employers that run wellness programs that include medical examinations can offer incentives up to 30 percent of the cost of self-only coverage.

PART B DRUG PAYMENT MODEL

On March 8th, CMS released a proposed rule to create and measure new drug payment models in Medicare Part B (covering physician offices and hospital outpatient departments). The model would involve a two-phase test comparing reimbursement levels and value-based purchasing options.

The proposal has received intense criticism from the medical community and many lawmakers. The House Energy & Commerce Committee recently held a hearing on the proposal on May 17th.

CMS initially announced that the first phase would be implemented in the second half of 2016 and the second phase would be implemented early in 2017; however, CMS confused lawmakers and stakeholders with a recent update in May on its website that final action on the model will not occur until March 2019. CMS contends that the model will still begin this year.

COMPREHENSIVE PRIMARY CARE PLUS

The Center for Medicare & Medicaid Innovation (CMMI) announced on April 11th its new Comprehensive Primary Care Plus (CPC+) initiative designed to save $2 billion over five years by moving away from FFS.

Physician practices may choose track one ($15 per patient as well as FFS payments) or track 2 ($28 per patient & reduced FFS payments + up-front comprehensive primary care payments).

CMS is currently recruiting payor participation with a target date for releasing applications to physician practices in July. CMS announced on May 27th that ACOs may apply to participate following criticism that they had initially been excluded. The initiative will begin in January 2017.

HOSPITAL IMPROVEMENT INNOVATION NETWORKS

On May 25th, CMS announced the creation of Hospital Improvement and Innovation Networks, a new, three-year payment model designed to achieve a 20 percent decrease in overall patient harm and a 12 percent reduction in 30-day hospital readmissions (from 2014 levels). The agency is soliciting contractors to support the networks through June 27th. Contractors will work as part of the Quality Improvement Organization (QIO) initiative to coordinate with hospitals and hospital associations, patients, and caregivers to implement evidence-based best practices.

***