Health Law Update
Overview

- Impact of Election Results
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Impact of Election Results

• A divided government
  o a return to the Obama/Boehner era when little gets done legislatively on the Hill
  o Lawmakers will go from one "fiscal cliff" to another as they struggle to pass continuing resolutions and not shut down the government
  o Both parties will simply try to take political advantage of the situation with the hope of gaining more control after the 2020 election
Impact of Election Results (Cont’d)

• US House of Representatives
  o Democrats are expected to return Nancy Pelosi (D-CA), Steny Hoyer (D-MD) and Jim Clyburn (D-SC) to their respective pre-2010 leadership positions as Speaker, Majority Leader and Majority Whip.
  o While they added a doctor, a nurse, and a former HHS secretary as incoming members, none will sit on a health care-related committee due to lack of seniority
  o A Democratic House rules out another GOP-led attempt to repeal and replace Obamacare, and sets House Democrats up to police the Trump administration's management of health care policy.
Impact of Election Results (Cont’d)

- According to House Democratic aides we've spoken to, they plan to pursue a multipronged health care strategy that includes:
  - Shoring up the ACA: Expect the House to pass legislation bolstering the ACA's insurance markets and fixing the cost-sharing reimbursement issue. The later issue saw some support in the Senate last year and could be one of the few pieces of legislation that makes it to the President's desk.
Impact of Election Results (Cont’d)

- According to House Democratic aides we've spoken to, they plan to pursue a multipronged health care strategy that includes:
  - Drug Pricing: Look for House Democrats try to reign in Pharma by making drug pricing one of their top issues. Also, leadership staff on the House Energy and Commerce Committee have indicated that incoming chairman Frank Pallone (D-NJ) WILL NOT make 340B reform a priority
Impact of Election Results (Cont’d)

- According to House Democratic aides we’ve spoken to, they plan to pursue a multipronged health care strategy that includes:
  - More oversight of HHS: Expect hearings on how the Trump administration has undercut the ACA, worked to roll back contraception coverage and teen pregnancy prevention and separated migrant children at the border. Democratic aides have indicated they will also focus on less politicized issues, like Medicare payment rates.
More House Oversight Activities include:

- Medicaid work requirements
- Oversight of the Justice Department's decision to back anti-ACA lawsuits
- Hearings policing drug companies for their price increases, which will take the focus off 340B
Impact of Election Results (Cont’d)

- At the committee level, Ways and Means Health Subcommittee Chairman Peter Roskam (R-IL) and subcommittee member Erik Paulsen (R-MN) both lost their race for reelection. With the retirement of Rep. Sam Johnson (R-TX), Lynn Jenkins (R-KS) and Diane Black (R-TN), Republicans will see very large changes in their membership on this subcommittee. Since Republicans currently hold an 11-7 majority on the subcommittee, these losses and retirements should mean no Republican will be removed from the subcommittee and one will be added. On the Democratic side, Richard Neal (D-MA) will become the next full committee chairman
At the Health Subcommittee, Lloyd Doggett (D-TX) is expected to jump over Mike Thompson (D-CA) to become the next chairman because he has more overall seniority in Congress. While Democrats are also expected to add up to 4 new members to this subcommittee.
Impact of Election Results (Cont’d)

- At the Energy and Commerce Committee, Frank Pallone (D-NJ) will become full committee chairman and Greg Walden (R-OR) will become the Ranking Minority Member. Pallone will focus his attention on oversight of the administration, fighting the opioid epidemic and lowering drug prices. He does have a reputation for "doing deals" across the aisle, which could make additional opioid funding a possibility
• US Senate
  o both parties could make progress on drug pricing and additional opioid legislation, but little else is expected to happen on the health care front
  o Senate Republicans like Bill Cassidy (R-LA) will continue to push for 340B reform, but any 340B legislation that passes the Senate should die in the Democratically-controlled House
Impact of Election Results (Cont’d)

- At the committee level, the Health Education Labor and Pensions (HELP) Committee saw no losses in its membership last night. Sen. Lamar Alexander (R-TN) will remain chairman and Sen. Patty Murray (D-WA) will remain the Ranking Member.

- At the Senate Finance Committee, Sen. Orin Hatch (R-UT), who is term-limited, will be replaced as chairman by Sen. Mike Crapo (R-ID) and Sen. Ron Wyden (D-OR) will remain Ranking Member. Sen. Crapo is widely considered to be a "banking and budget guy" who will focus more on financial issues than health care.
CAH Mileage Requirements

• The issue that never seems to die.....
  o California qui tam case
    ▪ Brought by the hospital's former CFO
    ▪ Turns on the interpretation of "or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive"
    ▪ And on the definition of "mountainous terrain"
    ▪ Added two other hospitals and requested certification as a class action
CAH Mileage Requirements (Cont’d)

- California case compared to the Oregon case
Final Rule: Physician Fee Schedule

• Evaluation & Management (E/M) Visits
  o For CY 2019 and CY 2020, CMS will continue the current coding and payment structure for E/M office/outpatient visits and practitioners should continue to use either the 1995 or 1997 E/M documentation guidelines to document E/M office/outpatient visits billed to Medicare
For CY 2019 and beyond, CMS is finalizing the following policies:

- Elimination of the requirement to document the medical necessity of a home visit in lieu of an office visit;
Final Rule: Physician Fee Schedule (Cont’d)

- For established patient office/outpatient visits, when relevant information is already contained in the medical record, practitioners may choose to focus their documentation on what has changed since the last visit, or on pertinent items that have not changed, and need not re-record the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated it as needed. Practitioners should still review prior data, update as necessary, and indicate in the medical record that they have done so;
Final Rule: Physician Fee Schedule (Cont’d)

- For E/M office/outpatient visits, for new and established patients, practitioners need not re-enter in the medical record information on the patient’s chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner may simply indicate in the medical record that he or she reviewed and verified this information; and

- Removal of potentially duplicative requirements for notations in medical records that may have previously been included in the medical records by residents or other members of the medical team for E/M visits furnished by teaching physicians
Final Rule: Physician Fee Schedule (Cont’d)

- Beginning in CY 2021, CMS is finalizing the following policies:
  - Reduction in the payment variation for E/M office/outpatient visit levels by paying a single rate for E/M office/outpatient visit levels 2 through 4 for established and new patients while maintaining the payment rate for E/M office/outpatient visit level 5 in order to better account for the care and needs of complex patients;
  - Permitting practitioners to choose to document E/M office/outpatient level 2 through 5 visits using medical decision-making or time instead of applying the current 1995 or 1997 E/M documentation guidelines, or alternatively practitioners could continue using the current framework;
Beginning in CY 2021, for E/M office/outpatient levels 2 through 5 visits, CMS will allow for flexibility in how visit levels are documented—specifically a choice to use the current framework, MDM, or time. For E/M office/outpatient level 2 through 4 visits, when using MDM or current framework to document the visit, CMS will also apply a minimum supporting documentation standard associated with level 2 visits. For these cases, Medicare would require information to support a level 2 E/M office/outpatient visit code for history, exam and/or medical decision-making;
Final Rule: Physician Fee Schedule (Cont’d)

- When time is used to document, practitioners will document the medical necessity of the visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary;
- Implementation of add-on codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care, though they would not be restricted by physician specialty. These codes would only be reportable with E/M office/outpatient level 2 through 4 visits, and their use generally would not impose new per-visit documentation requirements; and
Final Rule: Physician Fee Schedule (Cont’d)

- Adoption of a new “extended visit” add-on code for use only with E/M office/outpatient level 2 through 4 visits to account for the additional resources required when practitioners need to spend extended time with the patient
Final Rule: Physician Fee Schedule (Cont’d)

• Physician Self-Referral (Stark) Law
  o The final rule recognizes that the Bipartisan Budget Act of 2018 (BBA) codified previously created CMS regulations related to satisfaction of the writing requirement with regard to permitting a lease arrangement or personal service arrangement to continue indefinitely beyond the stated expiration of the written documentation describing the arrangement, if certain conditions are met
The final rule also acknowledges that the CMS policy which states that the writing requirement in various compensation arrangement exceptions can be satisfied by a collection of documents “including contemporaneous documents evidencing the course of conduct between the parties" was longstanding, but not contained in the regulations.
Final Rule: Physician Fee Schedule (Cont’d)

- The final rule goes on to amend the regulations to state that, for a compensation arrangement, the “writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.”
Lastly, per the BBA, the final rule amends the CMS "special rule" regarding temporary noncompliance with the signature requirement so that it no longer applies only to certain exceptions and that it can be used more than once every 3 years. Moreover, since the BBA was effective February 9, 2018, parties who would have otherwise been barred from using the special rule for temporary noncompliance with signature requirements because of the “3 year limitation” may begin to use it as of the effective date of the BBA.
Final Rule: Physician Fee Schedule (Cont’d)

• Communication Technology-Based Services
  o CMS is finalizing proposals to pay separately for two newly defined physicians’ services furnished using communication technology:
Final Rule: Physician Fee Schedule (Cont’d)

- Brief communication technology-based service, e.g. virtual check-in (HCPCS code G2012), Practitioners could be separately paid for the brief communication technology-based service when the patient checks in with the practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed; and

- Remote evaluation of recorded video and/or images submitted by an established patient (HCPCS code G2010), will allow practitioners to be separately paid for reviewing patient-transmitted photo or video information conducted via pre-recorded “store and forward” video or image technology to assess whether a visit is needed
Final Rule: Physician Fee Schedule (Cont’d)

• Provisions Expanding Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders under the SUPPORT Act
  o On an interim final basis, CMS is implementing a provision from the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act that removes the originating site geographic requirements and adds the home of an individual as a permissible originating site for telehealth services furnished for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for services furnished on or after July 1, 2019
Also on an interim final basis and via the SUPPORT Act, a new Medicare benefit category for opioid use disorder treatment services furnished by opioid treatment programs (OTP) under Medicare Part B is established, beginning on or after January 1, 2020.
Final Rule: Physician Fee Schedule (Cont’d)

• Therapy Services
  o The Bipartisan Budget Act of 2018 requires payment for services furnished in whole or in part by a therapy assistant at 85 percent of the applicable Part B payment amount for the service effective January 1, 2022
Final Rule: Physician Fee Schedule (Cont’d)

- In order to implement this payment reduction, the law requires CMS to establish a new modifier by January 1, 2019 and detail its plans to accomplish this in a final rule. Thus, CMS is finalizing its proposal to establish two new modifiers – one for Physical Therapy Assistants (PTA) and another for Occupational Therapy Assistants (OTA) – when services are furnished in whole, or in part by a PTA or OTA.

- However, CMS is finalizing the new modifiers as “payment” rather than as “therapy” modifiers, based on comments from stakeholders. These will be used alongside of the current PT and OT modifiers, instead of replacing them, which retains the use of the three existing therapy modifiers.
Final Rule: Physician Fee Schedule (Cont’d)

- CMS is also finalizing a de minimis standard under which a service is furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, instead of the proposed definition that applied when a PTA or OTA furnished any minute of a therapeutic service.
Final Rule: Physician Fee Schedule (Cont’d)

• Ambulance Fee Schedule
  o Per the Bipartisan Budget Act of 2018, temporary add-on payments for ground ambulance services were extended for 5 years; the three temporary add-on payments include:
    ▪ a 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas;
    • a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and
    • a 22.6 percent increase in the base rate for ground ambulance transports that originate in super rural areas
Final Rule: Physician Fee Schedule (Cont’d)

- The rule also increased the payment reduction from 10 percent to 23 percent for non-emergency basic life support transports of beneficiaries with end-stage renal disease for renal dialysis services furnished other than on an emergency basis by a provider of services or a renal dialysis facility.
Final Rule: Physician Fee Schedule (Cont’d)

• Medicare Shared Savings Program
  o CMS is finalizing the following policies:
    ▪ A voluntary 6-month extension for existing ACOs whose participation agreements expire on December 31, 2018, and the methodology for determining financial and quality performance for this 6-month performance year from January 1, 2019, through June 30, 2019
Final Rule: Physician Fee Schedule (Cont’d)

- Allowing beneficiaries who voluntarily align to a Nurse Practitioner, Physician Assistant, Certified Nurse Specialist, or a physician with a specialty not used in assignment to be prospectively assigned to an ACO if the clinician they align with is participating in an ACO
- Reducing the Shared Savings Program core quality measure set by eight measures, and
Final Rule: Physician Fee Schedule (Cont’d)

- promoting interoperability among ACO providers and suppliers by adding a new CEHRT threshold criterion to determine ACOs’ eligibility for program participation and retiring the current Shared Savings Program quality measure on the percentage of eligible clinicians using CEHRT