New Administration; New Congress: Federal Health Care Policy in the Year Ahead

PCMA

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FOLEY HOAG LLP

Speaker

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Agenda: What should we be watching for in the new Administration in 2017?

- Personnel – who will be filling the political roles in the new Administration?
- "Keeping the trains running on time": Managing the Medicare and Medicaid programs
- New Policies emerging from the Trump Administration
- ACA "repeal and replace"

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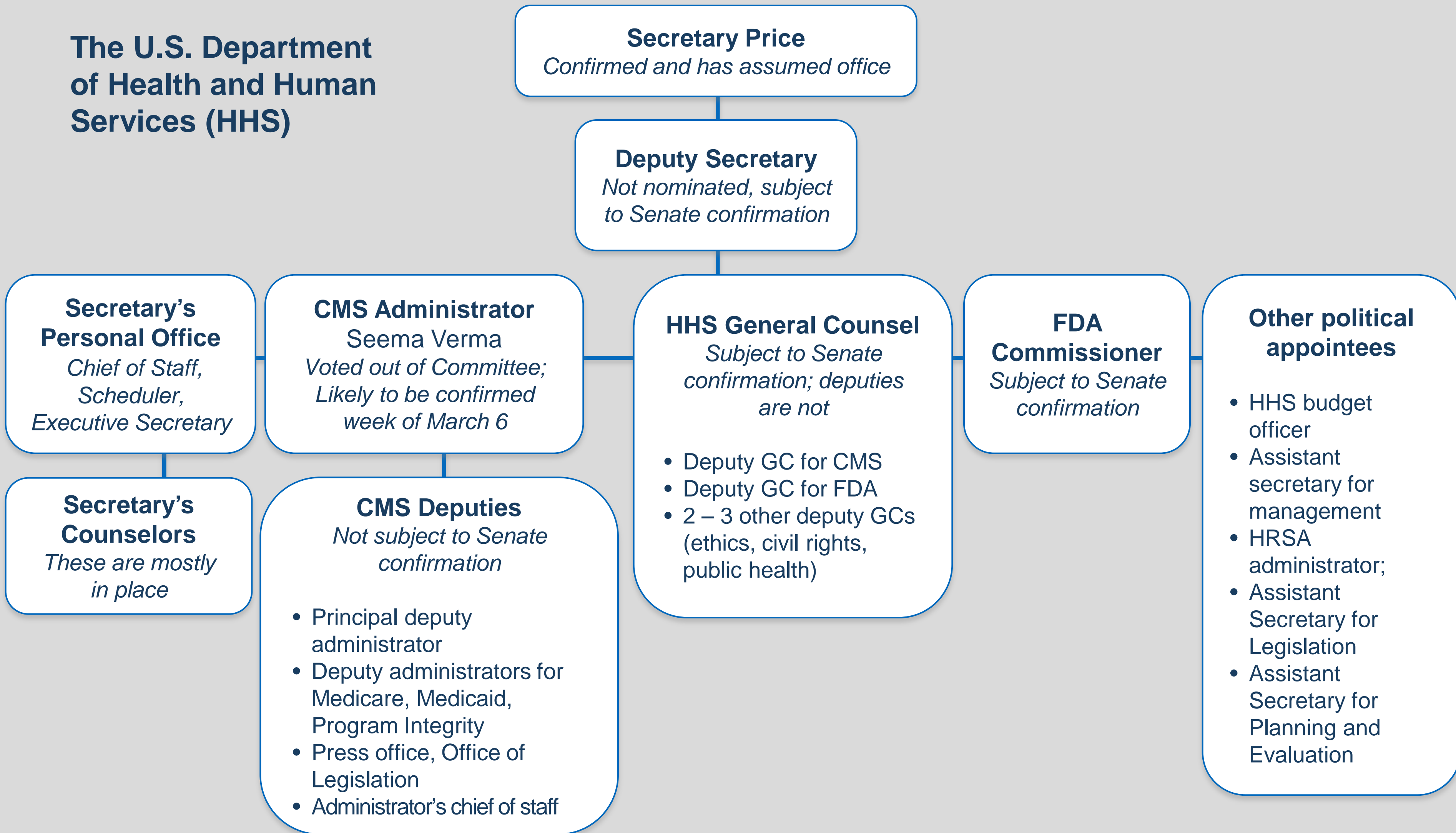
Personnel *Within HHS*



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Personnel

WHITE HOUSE

Domestic Policy Council

National Economic Council

White House Counsel

OMB

Director

OIRA

Health PAD

DEPARTMENT OF JUSTICE

Civil Division

Office of Legal Counsel

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Personnel – Observations

- President Trump is facing obstruction in getting his Cabinet nominees confirmed in terms of timing, although fairly good success in actually getting nominees through the Senate
  - He is being helped by the “no filibuster” rule adopted by the Senate for Cabinet nominees in 2013.
- The Trump Administration is behind other administrations in terms of staffing non-Senate confirmed political appointees
  - E.g., in Bush Administration, there was a Deputy Secretary, an Executive Secretary and CMS political deputies in the agency within the first week of the Administration.
- Lack of political appointees makes it very difficult to issue regulatory or sub-regulatory guidance.
  - CMS has only issued one “political” rule since 1/20/2017: The ACA market stabilization rule on February 15.

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Traditional Medicare and Medicaid

- In addition to all the political attention being paid to ACA implementation and “repeal and replace,” CMS also has statutory requirements to continue to operate the Medicare and Medicaid programs. Some key dates:
  - April 3, 2017: Finalize the Medicare Advantage/Part D call letter for Plan Year 2018
  - April – May 2017: Publish IPPS NPRM
  - June – July 2017: Publish PFS, HOPPS, dialysis PPS NPRM
  - August 2017: Publish final IPPS rule
  - November 2017: Publish final PFS, dialysis and HOPPS rules

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Traditional Medicare and Medicaid

- Medicare and Medicaid payment rules are enormously time consuming for staff (drafting rule; clearance process throughout HHS, OMB, and White House; publication in Federal Register; reviewing comments; responding to comments; writing final rule; clearing final rule).
- Career and political staff both need to be involved:
  - Departmental briefings
  - OMB briefings
  - White House briefings

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Traditional Medicare and Medicaid

- Other activities consuming staff time:
  - Issuance of sub-regulatory guidance throughout the year
  - Meetings with stakeholders
  - Policy and technical advice to Congress (e.g., SCHIP reauthorization)
- OGC
  - Advising its client (CMS, FDA, etc.) throughout rulemaking process
  - Defending department in litigation; coordinating with Department of Justice

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New Policies

- There are also be new policies implemented by Trump Administration
- These include both broad, government-wide policy proposals, as well as HHS-specific policy proposals
  - Government-wide proposals: concepts that change the operation or policy direction of the government
  - HHS-specific policy proposals: concepts that change the policy direction of the Medicare and Medicaid programs, FDA, etc.

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New Policies
Government-wide proposals

Executive Order (EO) easing regulatory burden of ACA

- Directive signed January 20, 2017
- Directs relevant cabinet agencies (HHS, DOL, DTR, IRS) to take all steps consistent with law to ease regulatory burden arising from ACA
- The EO creates no new authority for an agency to change policies under the ACA; rather, directs Cabinet agencies to take steps such as issuing new regulations or subregulatory guidance, repealing existing regulations, or changing interpretations of existing regulations.

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New Policies
Government-wide proposals

Regulatory Freeze

- Memo from WH Chief of staff to Cabinet agencies signed January 20, 2017
- Typical of similar directives from other Presidents going back to at least the Carter Administration
- Four main provisions:
  1. No regulation to Federal Register until it has been reviewed by a Presidential appointee
  2. Regulations sent to OFR but not published must be withdrawn
  3. For regulations published in OFR but not yet taken effect, delay effective date "60 days from the date of this memorandum."
     - This language is likely a mistake and is inconsistent with what prior Administrations have done.
     - Perhaps should read "60 days from the effective date of the regulation."
  4. "Consider" further postponing effective date through notice and comment rulemaking

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New Policies
Government-wide proposals

"Two For One" EO

- Signed January 31, 2017
- Two main provisions
    1. For every regulation proposed, the agency proposing the regulation must identify two other regulations for repeal.
    2. Cap on net costs of new regulations
- "Income transfer" rules are exempt from the EO, unless they impose requirements or other regulatory burdens on non-Federal entities.
    - Rules relating to Medicare and Medicaid could reasonably be considered income transfer rules.
    - Some CMS rules that OMB categorizes as income transfer rules include:
        - PFS, HOPPS, IPPS, Dialysis, home health, SNF PPS
        - Benefit and payment parameters rule for Exchange plans
    - Thus, not clear how much impact the EO will have on CMS rulemaking
    - Likely more significant for the FDA
- OMB will manage the process; time will tell how significant it is for Medicare/Medicaid rules.

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New Policies

- HHS/CMS-specific policies likely to be proposed, revisited or adopted in Trump Administration
  - Drug pricing
    - Greater transparency
    - Reimportation
    - Price regulation
    - Effect of any changes on PBM industry
  - Future of MACRA
    - Further delay?
    - New policy changes?
  - Future of CMMI and CMMI initiatives: bundled payment models, ACOs, payment for Part B covered drugs
  - Policy changes in the Medicare Advantage/Part D programs
  - Policy changes to Medicaid prescription drug rebate (PDR) program
  - HHS OIG: New safe harbors? Policy interpretations?

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ACA Repeal and Replace

- Obviously, all eyes on this in the year ahead. HHS heavily involved in three ways:
  - Issuing regulations and sub-regulatory guidance to undo many of the policies adopted by the Obama Administration
    - E.g., market stabilization rule issued February 15.
    - Many more likely to follow, potentially including:re-defining essential health benefits
  - Policy and technical advice to Congress
    - This relates as much to practical advice (what CMS can and cannot do) as well as timing (how soon can CMS do something)?
  - Implementing whatever Congress passes
    - Part D
    - ACA implementation

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Conclusion

- All stakeholders have a vested interest in how the new Administration approaches policy issues and its view toward regulation.
- We already know that this Administration has laid out an "anti-regulatory" agenda
  - Regulatory freeze
  - "Two for one"
  - ACA Burden Executive Order
- Organizations like PCMA monitoring high-profile issues in ACA
  - E.g., Part D policy initiatives
  - Policy revisions to Medicaid PDR program
- Continued smooth functioning of the Medicare and Medicaid programs is crucial to organizations like PCMA.
  - How to policy proposals like "two for one" EO affect these programs?

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