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Projecting & Tracking Health Care Developments in the Biden Administration, and FDA Predictions

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Presented by

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Agenda

1. Activities in Healthcare to Date
    i. Immediate Regulatory Issues
    ii. COVID-19 Response
    iii. Health Care Coverage and Access
    iv. Personnel
2. FDA Predictions

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Immediate Regulatory Issues

"Midnight" Regulations & Last Minute Rulemaking

BIDEN ADMINISTRATION RESPONSE TO LATE TRUMP RULEMAKING

Jan. 20, 2021 Memo of WH Chief of Staff to Agencies, "Regulatory Freeze Pending Review" – For final rules that are not yet effective, "consider postponing the rules' effective dates for 60 days from the date of this memorandum, . . . for the purpose of reviewing any questions of fact, law, and policy the rules may raise. For rules postponed in this manner . . . consider opening a 30-day comment period."

- Finalized and effective regulations require new notice and comment rule-making to alter, including simply deferring effective date
  - Medicare Most Favored Nation Demo (Part B Drug International Pricing Index) finalized on No. 27, 2020. Currently blocked by preliminary injunction
- Congressional Review Act (CRA) – Through March 2021, a simple majority vote can rescind certain "midnight" regulations. However, after a successful CRA vote, an agency may never issue a similar regulation without new express Congressional authority

Late Trump Administration Rulemaking Potentially Subject to Additional Review

Regulation	Summary	Finalized	Effective	Biden Administration Action
Clinic 340B Drug Discounts	Access to Affordable Life-saving Medications – Requires 340B program participating heath clinics to pass 340B price discounts on insulin and injectable epinephrine on to low-income patients	Dec. 23, 2020	Jan. 22, 2021	**Effective date deferred to Mar. 22, 2021**
PBM Rebates	Removes anti-kickback safe harbor for rebates from pharma manufacturers to Medicare plans and PBMs unless 100% of value is passed to consumer at point of sale. PCMA suit challenges as arbitrary and capricious	Nov. 30, 2020	Jan. 29, 2021	**Effective date deferred to Mar. 22, 2021**
Organ Procurement	Revisions to outcome measure requirements under conditions for coverage for Medicare organ procurement organizations	Dec. 2, 2020	Feb. 1, 2021	**Effective date deferred to Mar. 30, 2021**
Medicaid Drug Rebate Program	Facilitates value-based purchasing arrangements. Requires inclusion in the calculation of best price and AMP any pharma manufacturer financial assistance not directly benefitting the patient	Dec. 28, 2020	Mar. 1, 2021	
SUNSET Rule	All regulations expire after 10 years unless reviewed to confirm ongoing need and appropriate impact	Jan. 8. 2021	Mar. 8. 2021	
MCIT Pathway	Medicare Coverage of Innovative Technology Pathway allows for expedited coverage of "breakthrough" devices. Also creates new definition of "reasonable and necessary" for coverage to be informed by commercial payer policies	Jan. 14, 2021	Mar. 15, 2021	
2022 Medicare Advantage Rates	Final rate announcement of CMS methodology or setting 2022 payment rates for MA plans to inform plan development and submission of bids due in June. Normally finalized in April, the Trump administration finalized in January	Jan. 15, 2021	Due Apr. 5, 2021	
Notice of Benefit and Payment Parameters (2022)	Allows states to drop reliance on healthcare.gov Exchanges and instead rely on direct enrollment entities like web-based brokers to extend coverage. Codifies guidance allowing states to use ACA subsidies for short-term limited-duration health plans and association health plans. Other provisions to be finalized in later rulemaking	Jan. 14, 2021	Jan. 1, 2022	

Immediate HHS Regulatory To-Do List Based on New Law

CONSOLIDATED APPROPRIATIONS ACT OF 2021 (ENACTED DEC. 27, 2020) REQUIRED RULEMAKING

COVID Relief

- New HHS Provider Relief Fund (PRF) general distribution of approx. $30 billion ($3 billion in new funds)
- Update PRF reporting standards
- $22 billion for purchase of vaccines, therapeutics, diagnostics, and necessary medical supplies
- Approx. $8 billion vaccine distribution and related planning and tracking initiative
- $22 billion initiative to monitor and suppress COVID through testing, contact tracing, surveillance, containment, and mitigation

Medicare Reimbursement and Compliance

- Allow Medicare beneficiaries to receive mental health services via telehealth, including in the beneficiary's home
- Permitting occupational therapists to conduct the initial assessment visit and complete the comprehensive assessment with respect to certain rehabilitation services for home health agencies under the Medicare program
- Requires all manufacturers of Medicare Part B drugs to report ASP information in 2022 even if they lack a rebate agreement under the Medicaid Drug Rebate Program
- Create Medicare payment designation to allow a CAH or rural hospital with fewer than 50 beds to convert to a Rural Emergency Hospital
- Permitting direct Medicare reimbursement to physician assistants beginning in 2022

Surprise Billing Regulations

- The "No Surprises Act," enacted through the Consolidated Appropriations Act, requires rulemaking to be performed within 1 year, such as establishing:
  - The independent dispute resolution process for surprise bills
  - Audit requirements and regulations regarding establishing "qualifying amount" methodologies
  - A patient-provider dispute resolution process for uninsured individuals

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COVID-19 Response

COVID-19 Presidential Actions

EXECUTIVE ORDERS & ACTIONS ON JAN. 21, 2021 (DAY 2 OF BIDEN'S "10 DAYS OF PRESIDENTIAL ACTIONS")

	Executive Action (with Links)	Details
1	EO | **Improving and Expanding Access to Care and Treatments for COVID-19**	• Directs the Defense, HHS, and VA Secretaries to establish targets for the production, allocation, and distribution of COVID-19 treatments • Directs the HHS Secretary to evaluate and take any available steps to promote insurance coverage for safe and effective COVID-19 treatments and clinical care in Medicare, Medicaid, group health plans, and health insurance issuers • Directs the HHS Secretary with NIH to develop plans to support studies for promising COVID-19 treatments and future public health threats, to support research in rural locations, and to study long-term impacts of COVID-19 on health • Directs relevant agency heads to provide targeted surge assistance to critical care and long-term care facilities • Directs the HHS Secretary to issue recommendations to states and health care providers to increase the capacity of their health care workforce capacity
2	EO | **Establishing the COVID-19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats**	• Establishes the "COVID-19 Pandemic Testing Board," comprised of representatives from dep'ts and agencies to coordinate efforts • Directs the Treasury, HHS, and Labor Secretaries to facilitate provision of free COVID-19 testing for those who lack comprehensive coverage and to clarify insurers' obligations to cover testing • Directs HHS, Ed., and Homeland Sec. Secretaries and FEMA to support surveillance tests in certain settings and to expand access to testing • Establishes a Public Health Workforce Program, and requires planning for public health threats
3	EO | **Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats**	• Directs various agency and executive leaders (including HHS, Labor Dep't, Ed. Dep't, OMB, OSTP) to designate a senior official to lead their agency's work on COVID-19 and pandemic-related data issues • Directs agencies to review current public health data systems to advance innovation in public health data and analytics
4	EO | **Sustainable Public Health Supply Chain**	• Directs the State Dep't, Defense, HHS, and Homeland Sec. Secretaries to evaluate inventory of emergency response supplies, including PPE and the resources to effectively produce and distribute tests and vaccines at scale and to use all available legal authorities, including the Defense Production Act, to fill shortfalls • Directs these Secretaries to identify and analyze each agency's needs and capacity to produce/provide/distribute supplies • Directs HHS, Defense, and Homeland Sec. Secretaries to recommend how to address the pricing of pandemic response supplies (including whether to use GSA schedules for state, local, and tribal governments)

Note: On Jan. 20, 2021, Pres. Biden established the position of the "Coordinator of the COVID-19 Response and Counselor to the President" (COVID-19 Response Coordinator) to help the president and executive departments and agencies coordinate on the pandemic response

COVID-19 Presidential Actions

EXECUTIVE ORDERS & ACTIONS ON JAN. 21, 2021 (DAY 2 OF BIDEN'S "10 DAYS OF PRESIDENTIAL ACTIONS")

	Executive Action (with Links)	Details
5	EO | **Protecting Worker Health and Safety**	• Directs OSHA to issue revised science-based guidance on COVID-19 workplace safety within two weeks to reduce workers' exposure to COVID-19 and to consider emergency temporary standards, such as mask-wearing • Directs OSHA to launch a national program to focus OSHA enforcement efforts related to COVID-19 violations
6	EO | **Ensuring an Equitable Pandemic Response and Recovery**	• Establishes a COVID-19 Health Equity Task Force • Directs agency heads to work with the task force to strengthen equity in pandemic response
7	EO | **Supporting the Reopening and Continuing Operation of Schools and Early Childhood Education Providers**	• Directs the Ed. Secretary to develop evidence-based guidance for reopening, and keeping open, in-person learning
8	EO | **Promoting COVID-19 Safety in Domestic and International Travel**	• Requires travelers to wear masks in airports and in certain public transportation • Requires international travelers to show proof of a negative COVID-19 test, and imposes self-isolation and quarantine guidelines
9	**National Security Directive on U.S. Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness**	• Focuses on increasing the United States' role in the global pandemic response • Follows the Jan. 20, 2021, reversal of the previous administration's decision to withdraw from the World Health Organization
10	**Memorandum to Extend Federal Support to Governors' Use of the National Guard to Respond to COVID-19 and to Increase Reimbursement and Other Assistance Provided to States**	• Increases FEMA reimbursement to 100% of the costs states and tribal governments incur for deploying the National Guard or buying emergency supplies used to set up vaccination centers

Executive Orders **|** *Exercising authority that* Congress has given to the president alone or statements of administration policy that direct agencies to develop regulations or substantive law

President Biden's "American Rescue" COVID Relief Legislative Plan*

OVERVIEW AND HEALTHCARE PRIORITIES

Additional $20B for National Vaccine Program

- Encourage access for more priority groups (65+, essential workers)
- Establish more vaccination sites through FEMA, Nat'l Guard, FQHCs, and pharmacies
- Increase vaccine supply using Defense Production Act
- Use PHS Commissioned Corps for vaccinations and hire a contact tracing workforce
- Public education campaign to encourage vaccination

Additional $50B Testing Initiative

- Purchase rapid tests & expand lab capacity
- Implement regular testing protocols for schools and local governments

**Dec. 2020 Consolidated Appropriations Act provided $30B for vaccination program and $20B for testing program*

Health Coverage Expansion

- Subsidize Continuation of COBRA coverage through Sept. 2021
- "Expand and increase the value of the Premium Tax Credit"
- Ensure ACA Exchange enrollees pay no more than 8.5 % of their income for coverage

Other Provisions

- $1,400 per person stimulus checks (in addition to $600 previously enacted)
- Extend unemployment comp to Sept. 2021
- $15 minimum wage
- Increase funding for long term care residents and workers and in prison settings
- $30B into the Disaster Relief Fund + $10B investment into domestic manufacturing for pandemic supplies

Parameters of Democratic Control of Senate

LEGISLATIVE OPPORTUNITIES AND RESTRAINTS IN 50-50 SENATE WITH VP BREAKING TIE VOTES

51 Votes for a Simple Majority

- Cabinet and judicial nominations may be easily confirmed
- Set agenda for Committees and Senate floor
- Pass low profile legislation
- Senate rules may be changed (eliminate filibuster; expedited impeachment for former POTUS)

60 Votes to Pass Cloture Motion

- Rules require supermajority of 60 votes to invoke "cloture" to end debate and move to final vote on passage of bill
- Failure to invoke cloture is considered a "filibuster"
- Effectively requires supermajority support to pass major legislation
- Use has more than doubled over 20 yrs

51 Votes for "Budget Reconciliation"

- Not subject to filibuster
- Legislation must be limited to changing either (1) taxes, (2) entitlement spending, or (3) debt limit
- Limited to only one bill addressing each topic per budget resolution
- Multi-stage process required: (1) include directives in budget resolution; (2) Committees draft corresponding changes to underlying law; (3) expedited final vote
- Used by Congress 25 times since 1980

Eliminating the Senate Filibuster? Considerations for Democrats . . .

- **Leadership likely to maintain perpetual threat of eliminating filibuster in order to enforce party discipline on other votes**

Factors In Favor of Eliminating Filibuster	Factors In Favor of Maintaining Filibuster
Democratic base is owed substantive legislative wins (add seats to Supreme Court; create new states; single-payer; Green New Deal)	Democratic majority status in Congress is razor-thin. Threat of losing majority in electoral backlash against overreach (i.e., 1994, 2010)
Pressure on Majority Leader Schumer (NY) and other Dem incumbents to avoid primary challenge from left; 13 Dem Senate seats up in 2022	Swing state Democrats may face tight reelection race in 2022: Raphael Warnock (GA); Mark Kelly (AZ)
Once in generation opportunity to pass long-standing, major reforms	Expanded legislative power would be used by Republicans against Democrats when they next gain back 1 Senate seat

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Health Care Coverage and Access

Executive Order on Strengthening Medicaid and the Affordable Care Act

SIGNED JAN. 28, 2021 AS A PART OF BIDEN'S "10 DAYS OF PRESIDENTIAL ACTIONS"

"It is the policy of my Administration to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American."

"Special Enrollment Period" (SEP)

- Directs the HHS Secretary to consider existing authorities to establish a **SEP for uninsured and under-insured Americans** to seek coverage through the Federally Facilitated Marketplace
- **Note**: On Jan. 28, CMS announced a Feb. 15 - May 15 SEP for all eligible consumers (uninsured *and* currently-enrolled members)

"Revocation of Certain Presidential Actions and Review of Associated Agency"

- Revokes Pres. Trump's "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal" and "Promoting Healthcare Choice and Competition Across the United States" executive orders
- Directs Agency Heads to identify Agency Actions related to the revoked executive orders and to **consider whether to suspend, revise, or rescind, and (as applicable) publish proposed rules to suspend, revise, or rescind the Agency Actions**

"Immediate Review of Agency Action"

- Directs Agency Heads to review all Trump-era Agency Actions to **determine whether any of them are inconsistent with the policy of protecting and strengthening Medicaid and the ACA.** Agency heads must review demonstrations, waivers, and policies that may reduce coverage or otherwise undermine Medicaid or the ACA as well as policies or practices that may:
  - Undermine ACA protections for people with pre-existing conditions, including complications related to COVID-19
  - Undermine the Health Insurance Marketplace or the individual, small group, or large group markets for health insurance
  - Present unnecessary barriers to individuals and families attempting to access Medicaid or ACA coverage (including for mid-year enrollment)
  - Reduce the affordability of coverage or financial assistance for coverage (including for dependents)
- Directs Agency Heads to consider **whether to suspend, revise, or rescind (as applicable) propose rules to suspend, revise, or rescind the Agency Actions** inconsistent with the policy of protecting and strengthening Medicaid & the ACA
- Directs the Agency Heads to consider whether to take additional Agency Actions to more fully enforce the policy of protecting and strengthening Medicaid & the ACA

"Agency Actions" *include existing regulations, orders, guidance documents, policies, and any other similar agency actions*
"Agency Heads" *include the HHS, Treasury, and Labor Secretaries and other heads of agencies and departments with authorities and responsibilities related to Medicaid and the ACA*

ACA Marketplaces – Immediate Review of Trump-Era Agency Action

HHS CONSIDERING NEW ADMINISTRATIVE ACTIONS TO "PROTECT AND STRENGTHEN" THE ACA

Marketplace-Related Actions During the Trump Administration*	Potential Responses by the Biden Administration	Requires New Rulemaking?
Reduce funding to navigators. Require only 1 navigator program to operate in each federal Marketplace	Increase funding for marketing and promotion. Restore navigator grant levels. Restore minimum number of 2 navigator programs in federal Marketplaces and require maintenance of physical presence in the service area.	
Allow states to drop reliance on healthcare.gov Marketplaces and instead rely on direct enrollment entities like web-based brokers to extend coverage	Maintain requirement that enrollment is performed through healthcare.gov. Strengthen consumer protection standards for commercial we-broker sites	✓
Codify less restrictive standards for the review of state requests for "section 1332 waivers" from certain ACA requirements	Revise regulatory standards for waivers to limit exceptions to ACA requirements and to prevent reductions in access, affordability, or comprehensive benefits	✓
Reduction in user fees paid by Marketplace plans	Restore user fees to prior levels. Such fees finance marketplace operating expenses, including compliance oversight, navigator assistance, and marketing and outreach	✓
Permit enrollment in short-term, limited duration plans for 364 days, with an option to renew for 36 months	Limit future enrollment in such plans. Require more comprehensive benefits	✓
Classify some association health plans (AHPs) as single employer plans and therefore exempt from individual and small group coverage standards	Restore prior classifications and standards	✓
Shorten open enrollment periods for the federal Marketplace	Increase the enrollment period for the federal Marketplace	✓

***Note** - On Nov. 10, 2020, Supreme Court heard oral arguments in *California v. Texas*. As Congress eliminated the individual mandate tax penalty from the ACA in 2017, Texas argues that the individual mandate is now unconstitutional and that the entire ACA should be overturned due to "lack of severability" between the law's provisions. An opinion is expected between Feb. – June 2021 addressing plaintiffs standing, the individual mandate, and its severability from the rest of the ACA.

Medicaid – Immediate Review of Trump-Era Agency Action

HHS CONSIDERING NEW ADMINISTRATIVE ACTIONS TO "STRENGTHEN MEDICAID"

Medicaid-Related Actions During the Trump Administration	Pathways for the Biden Administration	Challenges/Considerations for the Biden Administration
Work Requirements. A 2018 CMS policy permitted states to apply for use of 1115 waivers to test Medicaid work requirements **Block Granting.** On Jan. 8, 2021, the Trump admin. approved a 10-year 1115 waiver for TN's Medicaid program to use a lump sum arrangement. In Jan. 2020, CMS issued a letter to state Medicaid directors inviting states to design demonstrations that used block grants	• The Biden administration might attempt to withdraw approved waivers (which states can challenge) or decline to renew or renegotiate waivers • The Biden administration would have the authority to reverse CMS' 2018 policy change. For future 1115 Waiver requests, the Biden administration might release guidance requiring states to demonstrate they have considered the impact of the waiver request on coverage and that waivers that decrease coverage will not be considered for approval	• On Jan. 4, 2021, former HHS Sec. Seema Verma issued a letter to states with 1115 waivers requesting Medicaid Directors sign a "Letter of Agreement" that would establish procedural rights for future waiver withdrawals by the Biden admin. while also giving states the opportunity to appeal. • Stakeholders have petitioned CMS challenging procedural aspects of the letter, particularly considering the current Good Guidance policy • The Supreme Court has agreed to hear a case, *Azar v. Gresham*, challenging HHS's approval of work requirements for Arkansas and New Hampshire. Oral arguments will likely occur in the summer.

*Section 1115 of the Social Security Act authorizes the HHS Secretary to grant **"1115 Waivers"** to permit states to waive compliance with certain Medicaid requirements to test various models through demonstrations. CMS must approve the demonstration.*

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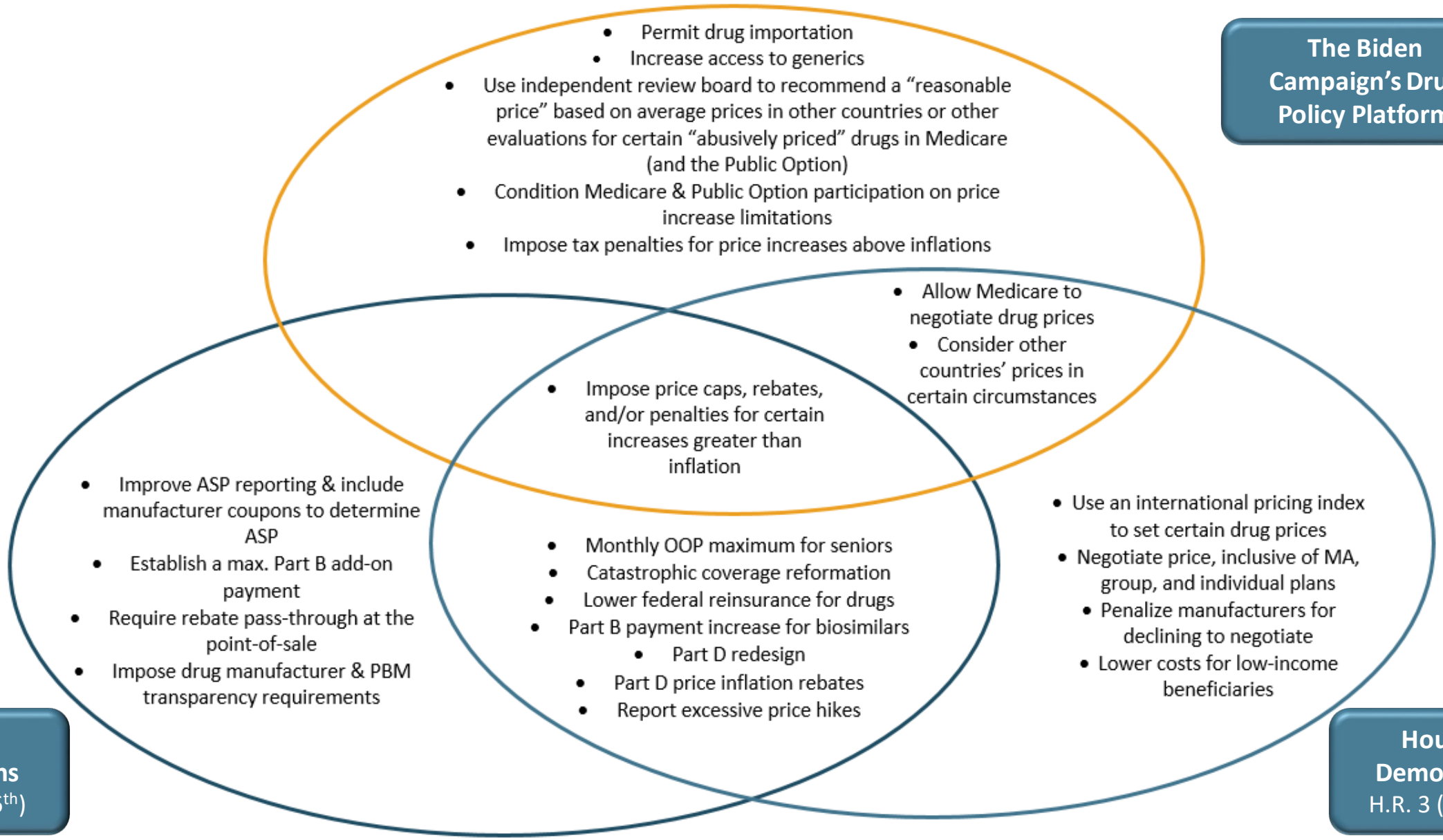
Prospects for Agreement on Prescription Drug Pricing Legislation

Drug Pricing Legislation

DRUG PRICING LEGISLATION & OVERLAPPING POLICY PRIORITIES



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Personnel

Key Personnel

HEALTH LAW & REGULATIONS EMERGE FROM NEGOTIATION AMONG MULTIPLE STAKEHOLDERS

Dep't of Health & Human Servs. (Nominees & Appointments)

- **Secretary of HHS**
  - **Nominated** | Cal. AG Xavier Becerra
    - **Acting |** Norris Cochran (until Becerra confirmed)
- **Deputy Secretary |** Andrea Palm
- **CMS Administrator |** ? (Liz Richter acting)
- **FDA Commissioner |** ? (Janet Woodcock acting)
- **CDC Director |** Dr. Rochelle Walensky
- **COVID-19 Equity Task Force Chair |** Dr. Marcella Nunez-Smith
- **Surgeon General |** Dr. Vivek Murthy

The White House (Appointments)

- **Chief of Staff |** Ron Klain
- **Director of OMB |** Neera Tanden (Nominee)
- **Director of the National Economic Council |** Brian Deese
- **Director of the Domestic Policy Council |** Susan Rice
- **Chief Medical Adviser on COVID-19 to the President |** Dr. Anthony Fauci

The Biden Administration must fill nearly 4,000 political appointee positions, 1,200 of which require Senate confirmation. This usually takes more than 1 year.

Congressional Leadership

U.S. Senate

- **Senate Majority Leader |** Sen. Chuck Schumer (D-NY)
- **Senate Minority Leader |** Sen. Mitch McConnell (R-KY)
- **Key Committee Leadership**
  - **Finance**: Sen. Ron Wyden (D-OR)
    - **RM**: Sen. Mike Crapo (R-ID) (presumed)
  - **HELP**: Sen. Patty Murray (D-WA)
    - **RM**: Sen. Richard Burr (R-NC) (presumed)

U.S. House of Representatives

- **Speaker of the House:** Speaker Nancy Pelosi (D-CA-12)
- **Key Committee Leadership**
  - **Energy & Commerce |** Rep. Frank Pallone (D-NJ-06)
    - **RM:** Rep. Cathy McMorris Rodgers (R-WA-05)
  - **Ways & Means |** Rep. Richard Neal (D-MA-01)
    - **RM**: Rep. Kevin Brady (R-TX-08)

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FDA Predictions

Expect more guidance/more activity

Removal of Procedural Roadblocks

- The prior Administration instituted policies to slow development of regulations, which the Biden Administration has already begun to address
  - Executive Order 13771 (Jan 30, 2017) – to publish a new regulation, and agency needed to remove two regulations
    - This order was revoked by President Biden on his first day in office
- The prior Administration put limits on the issuance of guidance that are likely to be removed as well

Personnel

Potential Impact

- HHS Secretary Xavier Becarra
  - Strong proponent of the ACA, Women's Health Issues, and a recent focus on the Opioid Crisis
  - Background and interests may influence selection of FDA Commissioner
  - Likely will pull back on prior Administration approach to overruling FDA with regard to operations, but may facilitate more coordination on FDA issues that impact access to affordable healthcare
- FDA Commissioner
  - No one has been nominated to date
  - Most public discussion has focused on bringing in a career FDA person (Janet Woodcock), Obama Administration alum (Josh Sharfstein), or previous commissioners (Mark McClellan)
  - Commissioner will likely come in with their own set of priorities, though the immediate priority for the foreseeable future is Covid-19

Covid-19

Medical Devices

- CDRH issues a number of guidances to facilitate access to personal protective equipment, telehealth tools, diagnostic test components and other products
- CDRH has led the agency, by far, in the issuance of Emergency Use Authorizations (EUA), though processing time has slowed over the last several months as the Agency is overwhelmed with EUAs
- CDRH has been looking to outsource some review functions beyond traditional 3rd party review
  - E.g., review of laboratory developed tests
- Unlikely in the near term to see major changes in the CDRH approach beyond, perhaps, laboratory developed tests (LDTs) and enforcement

Covid-19

Medical Devices: LDTs and Device Enforcement

- Laboratory Developed Tests for Covid-19 currently do not require FDA review
  - At the start of the pandemic, review of these tests was required by FDA
  - In August, the Department of Health and Human Services overruled FDA in a very public and unusually way, changing the FDA policy against the apparent wishes FDA staff and leadership
  - FDA has been focused on looking at third-party review mechanisms which would address the real concern of review delays with LDTs but could help bring tests back under FDA oversight
  - As approved tests become more readily available, and systems are put in place to handle reviews in a timely fashion, it is more likely that FDA will look to require review of LDTs for Covid-19
    - Action won't be taken until its clear that test capacity won't be meaningfully diminished
- Enforcement, particularly with respect to consumer devices for Covid-19, may increase
  - To date, the Federal Trade Commission has taken the lead with regard to policing consumer products
  - We may begin to see more coordinated enforcement/joint warning letters with regard to products promoted for Covid-19

Covid-19

Pharmaceuticals and Vaccines

- The vaccine pathway is likely to continue as is, and has been one of the bigger success stories for FDA with regard to Covid-19
- With regard to pharmaceuticals, though, CDER has generally not taken advantage of its ability to relax standards with regard to review of products for Covid-19 with limited exceptions where there was keen political interest
- We *might* see some improvement on that front in the Biden Administration as the reality of a long-term pandemic is sinking in, and the need for preventive and therapeutic treatments becomes more obvious, and with Covid-19 being a focus of the Biden Administration
- We also are likely to see more enforcement with regard to products making Covid-19 claims, similar to the device spaces

Longer Term Policies

Public Health Emergencies

- Opioid Crisis
  - Expect a much greater focus on addressing the opioid epidemic
  - Speeding access to products which can help address the crisis
  - Could see CDER take a more progressive route to speeding products, similar to the CDRH approach
- Vaping
  - Expect enhanced requirements
  - Further restrictions
- Drug Access/Pricing/Costs
  - The Biden Administration is focused on healthcare costs
  - Although the initial focus is on drug pricing issues, it is likely that FDA's roll in the cost equation
    - Efficiencies in review?
    - Speeding access to generics, and substitutable biosimilars?
    - Drug re-importations?
    - Will the unapproved drug initiative return (revoked by HHS at the end of the prior administration)

Reforming Diagnostics Regulation

Bringing LDTs, generally, within the scope of FDA regulation

- During the Obama Administration, a framework was released to bring LDTs, which are generally exempt from FDA regulation as a matter of enforcement discretion, under FDA purview
- There are advocates on both sides with regard to whether FDA should or should not regulate LDTs
  - The last two Congresses, there also has been legislation to address the issue, and put LDTs on a level playing field with *in vitro* diagnostics (IVDs) that FDA regulates.
- There might be a renewed push for bringing LDTs within the scope of FDA regulation, which could be impacted by the COVID-19 response
  - If an issue came to light with COVID-19 LDTs (e.g., performance problems with these test) that could create a push in favor of broad LDT regulation
  - If there are no issues, or FDA cannot address the review issues that arose LDTs (which led to delay with COVID-19 EUAs for LDTs), action could be less likely

Enforcement Activity

Expect More Warning Letters

- Warning Letters dropped substantially during the prior administration, which is a trend that is unlikely to continue
- Potential Areas of Focus
  - COVID-19
  - Prescription Drug Promotion
  - Drug Compounding
  - cGMP / Quality System Violations

Thanks To My Colleagues

EBG AND AFFILIATED ENTITIES

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  - 125 health care attorneys
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- Legal practice driven by federal and state law and regulation
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- The National Health Advisors are:
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  - Health Lawyers
  - Federal Regulatory Veterans

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Questions?

Contact Information

If you have any questions, feel free to contact me at --

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