Policy Brief

December 4, 2020

Changing of the Guard: What a New Administration Could Mean for Health Policy

With the swing states of Arizona and Wisconsin certifying their election results, the transition to a new White House seems assured. President-elect Joe Biden's team is wasting no time, already exploring new public policy ideas on issues of national security and the public health emergency. The Biden Administration's policy priorities are wide-ranging, spanning topics like prescription drugs, lowering the cost of care and reducing racial and ethnic disparities in health outcomes. Read more on what the changing of the guard could mean for health policy.

What tools could the new Administration use to modify Trump-era policy?

The Biden Administration could leverage the Congressional Review Act (CRA), a law that allows Congress to overturn recently-released regulations. Under the CRA, the President and Congress must both agree to disapprove a rule, blocking it from taking effect. To be considered, a regulation must be evaluated independently (i.e. the CRA cannot overturn regulations "in bulk"). If Congress and the President do *not* agree, the President can always issue Executive Orders. An Executive Order cannot be overturned by Congress; only a sitting President may undo an existing Executive Order.

Will the Biden Administration use these tools to reverse health policy?

Perhaps in some cases, but not across the board. In alignment with the President-elect's policy platform, the Biden Administration is likely to focus on scaling back Medicaid work requirements,

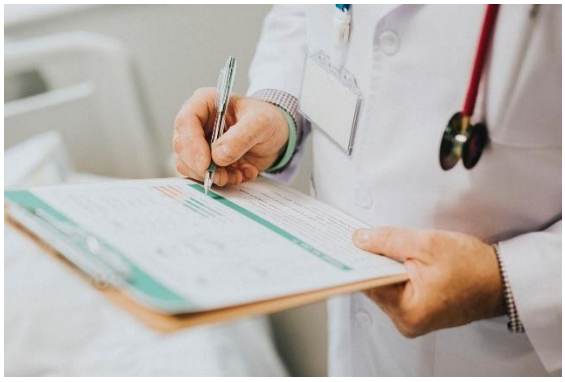
improving antidiscrimination protections for LGBTQ+ persons and limiting short term plan offerings on the Health Insurance Exchanges.

What about Stark and "antikickback" reforms?

It remains to be seen how the Biden Administration will approach these recent reforms; it is unlikely that the recently-released Stark modernizations will be undone. The need to reform the Stark and antikickback provisions are understood and supported by policymakers across the political spectrum. Biden's team may see opportunity to build on this year's regulations, but this will likely be done in collaboration with the broader health care industry.

What health policy priorities will guide the Biden Administration?

The new Administration has repeatedly expressed its commitment to strengthening the Affordable Care Act, likely by restoring enrollment-related funding. The Biden Administration is also concerned with supporting Medicaid expansion, particularly in non-expansion states. Substance Use Disorders (SUDs) have also been a longtime priority of the President-elect. The Biden Administration is expected to prioritize additional funding for SUD initiatives and pivot from punitive sentencing for drug misuse to a public health strategy. The President-elect's full policy platform is available here.



Final Rules Amending Stark and Anti-Kickback Statutes

HHS released two long-awaited final rules that revise the Physician Self-Referral Law (Stark Law), and the Anti-Kickback Statute (AKS). The rules seek to promote value-based arrangements by creating new exceptions to the Stark Law, additional safe harbors under the AKS and new definitions of key terms. The changes are effective January 19, 2021, with the exception of the Stark Law's definition of "group practice," which is set for January 1, 2022. While President-elect Biden may put a hold on these rules until his Administration reviews them, a total reversal is unlikely given the bipartisan support for regulatory modernization. Efforts to continue perfecting these rules are more likely; for example, members from the House's Health Care Innovation Caucus announced that they will pursue additional changes. For a detailed summary of the new rule on Stark, click here and for AKS, here. Below are key highlights from the rules.

Key Changes to Stark

Three new exceptions were created.

Full Financial Risk Exception: Applies to participants in a value-based enterprise that have assumed the full financial risk for the cost of items and services provided to patients and covered by the applicable payors. For Medicare beneficiaries, this means that participants would be responsible for all items and services covered under Medicare Part A and B.

Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician Exception: Protects remuneration paid under a value-based arrangement where the physician accepts the risk for at least 10% of the total value of the remuneration. The nature and extent of the physician's risk must be set in writing.

Value-Based Arrangements Exception. Unlike the other two exceptions, this exception does not require participants to assume any financial risk. Therefore, it includes additional safeguards, such as a signed writing and annual monitoring requirements.

Three key definitions were revised.

Definitions were updated for "Fair Market Value," "Commercial Reasonableness" and "Volume and Value of Referrals."

Key Changes to AKS

Three new safe harbors were created.

Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency: Protects only in-kind remuneration. The parties in this arrangement must establish outcome measures to advance the coordination and management of care for the target patient population. The recipient must contribute at least 15% of either the offeror's cost or the fair market value of the remuneration.

Value-Based Arrangements with Substantial Downside Risk: Protects both in-kind and monetary remuneration paid under a value-based arrangement where a participant assumes a meaningful downside risk. The amount of risk depends upon the methodology used.

Value-Based Arrangements with Full Financial Risk: Provides the greatest flexibility but requires the most risk. It protects both in-kind and monetary remuneration.

Four existing safe harbors were revised.

The rule amended safe harbors on Personal Services, Management Contracts and Outcomes-Based Payments; Electronic Health Records; Warranties; Local Transportation; and Beneficiary Incentives. Notably, CMS revised the Local Transportation waiver to expand mileage limits for rural areas from 50 to 75 miles and clarified that the protection includes transportation using rideshare services.

The Trump Administration Releases Most Favored Nations Model

Even as the transition to the Biden Administration begins, the Trump Administration released several drug pricing initiatives, likely in an effort to keep its campaign promises. One of the largest initiatives is the mandatory Most Favored Nation (MFN) Model, which aims to lower prices by tying the cost of Medicare Part B drugs to the lowest price charged in similar counties. Policy experts believe that this model will likely be challenged in court, and if it does survive, may be rolled back under the Biden Administration. In addition to the MFN Model, a drug rebate rule was also released that would eliminate Medicare Part D drug rebates for "middlemen," and President Trump announced he would eliminate the Unapproved Drug Initiative that has allowed drug makers to raise prices for old medicines.

Most Favored Nation (MFN) Model Structure

The Most-Favored Nation (MFN) Model works by tying the price of prescription drugs to the lowest international prices and paying providers a flat add-on amount for each drug dose, instead of an add-on of the percentage of the cost. Under this model, providers would have their Medicare Part B payments reduced with the expectation that manufacturers will also lower the prices for the drug. The model:

- Is a mandatory, national, seven-year model beginning on January 1, 2021.
- Includes 50 high-cost drugs and biologics administered in the outpatient setting.
- Uses a blending formula that takes into account the lowest adjusted international price between countries with a similar GDP as the U.S. to determine the MFN price.
- Phases-in a new payment formula, with years one through four using 25% of the MFN price and years five through seven using 100% of the MFN price.
- Excludes certain types of hospitals and clinics including cancer hospitals, children hospitals and Federally Qualified Health Centers (FQHCs).

Critiques of the Drug Pricing Initiatives

Pharmaceutical companies strongly oppose the MFN rule, believing that it will restrict access to innovative drugs and that the Administration is overextending its authority. Other providers, particularly oncologists, believe that CMS reducing reimbursement will lead to increased financial

burden on providers, as manufacturers may not lower their price to compensate for the MFN price. According to CMS' projections for similar proposals, eliminating rebates will likely not significantly impact patients, however, it would provide billions of savings for drug makers while increasing government spending. President Trump's announcement to eliminate the Unapproved Drug Initiative received more support, as policy experts agree that pharmaceutical companies used it as a loophole to create an artificial monopoly, resulting in raised prices.

Drug Pricing Initiatives' Longevity

The MFN model will likely be challenged in courts by the prescription drug companies. Even if the rules do survive, they will not be finalized by President-elect Biden's swearing in, providing an opportunity to roll back or eliminate this rule. The drug rebate rule, which has been supported by pharmaceutical companies, and the elimination of the Unapproved Drug Initiative may have a higher chance of survival.

Physician Fee Schedule Final Rule Released

CMS has finalized the 2021 Physician Fee Schedule rule, outlining how physicians participating in Medicare will be paid for care delivery. The final rule reevaluates codes for Evaluation and Management (E/M) visits, extends select telehealth flexibilities beyond the pandemic and allows nonphysician practitioners to supervise diagnostic tests. The rule also finalizes across-the-board payment reductions to many specialty services. The official rule language is scheduled to be published on December 28th. Until then, the regulation can be read on the public inspection desk. An outline of the rule will be included in the next Policy Brief.

Outpatient Prospective Payment System Final Rule Released

CMS has finalized the 2021 Outpatient Prospective Payment system rule, which contains policies impacting outpatient payments and services provided in the outpatient setting. Key finalized policies include the elimination of the Inpatient Only List by January 2024, the addition of five new procedures requiring prior-authorization, the addition of eleven new procedures to the Ambulatory Surgical Center covered list and changes to the Overall Hospital Star Ratings. CMS is continuing the current 340B payment policy of paying ASP minus 22.5% for 340B-acquired drugs and will continue to consider "the appropriateness of using 340B hospital survey data to set future payment rates for 340B drugs." An outline of the rule will be included in the next Policy Brief.

Senators Release COVID-19 Relief Proposal

A bipartisan group in the Senate introduced a $908 billion COVID-19 relief proposal aimed at breaking the current congressional stalemate. The package includes $35 billion for the health

care Provider Relief Fund and a liability provision that provides a *temporary* suspension of any liability-related lawsuits at the state or federal level associated with COVID-19. The group is comprised of Sens. Mitt Romney (R-Utah), Bill Cassidy (R-Louisiana) and Susan Collins (R-Maine), among others. However, when asked about his position on the bill, Senate Majority Leader Mitch McConnell stated on Tuesday that "We just don't have time to waste time," and a spending bill and pandemic relief provisions will "all likely come in one package." The current Continuing Resolution expires on December 12th and Congress will need to act before then to avoid a government shutdown.

Updates on COVID-19 Regulations

AHPA continues to follow new COVID-19 regulations, guidance and other government actions. The updates below are the latest guidance and other developments since November 20th to help mitigate the impacts of COVID-19. For earlier COVID-19 regulations and guidance, visit the previous Policy Brief.

HHS Issues Clarification on Provider Relief Funds

- HHS issued two clarifications related to Provider Relief Fund reporting. Expenses for capital equipment, facilities projects and inventory may be fully expensed when the purchase was directly related to the prevention, preparation for and response to COVID-19. Reporting of net patient revenue should not include any payments to or from third parties that relate to care not provided in 2019 or 2020.

FDA Authorizes First At-Home COVID-19 Test

- The FDA has announced an emergency use authorization for the first COVID-19 diagnostic test meant for self-testing at home. The Lucira COVID-19 All-in-One Test Kit is approved for individuals 14 and older and can provide results in 30 minutes or less.

A Look at the Federal Register

Medicare Physician Fee Schedule Final Rule for CY 2021

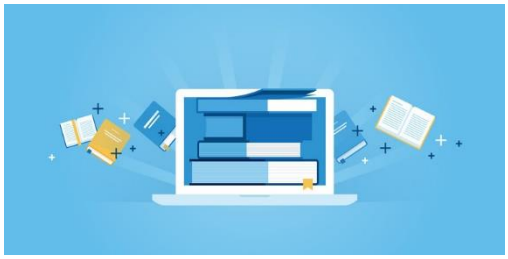
CMS has released the final rule for the Medicare Physician Fee Schedule (PFS) for calendar year 2021. The final rule includes policy changes for Medicare payments under the PFS and other Medicare Part B issues. **The rule is effective January 1, 2021.**

Medicare Hospital Outpatient Prospective Payment System for CY 2021

CMS has released the final rule governing how providers will be reimbursed for care provided in the outpatient and ambulatory surgical center settings. **The rule is effective January 1, 2021; comments will be due 30 days after the rule's publication on the Federal Register.**

Agency Information Collection: Changes to Medicare Cost Reports

CMS has proposed changes to the Medicare Form CMS-2552-10, commonly known as the *Hospital and Health Care Complex Cost Report*. Included in the proposal is the creation of a new worksheet to capture median Medicare Advantage negotiated charges. **Comments are due on January 11, 2021.**



AHPA Resources

- Rule Summary: Additional COVID-19 Policy and Regulatory Revisions
- Webinar Recording: FY 2021 IPPS Final Rule

IN OTHER NEWS

Biden's Cabinet and White House Picks: Who They Are, What We Know – WSJ

During ACA Open Enrollment, Picking a Plan Invites New COVID-19 Complications – KHN

CVS, Walgreens to Give Covid-19 Shots at Nursing Homes – Bloomberg

Racial Equity; A Physician on the Health Effects of Racism – Health Affairs

HHS Launches New Portal to Help You Join Clinical Trials – HHS

Hospital In-Home Care During the COVID-19 Pandemic – Lexology

Op-Ed: The Rotting of the Republican Mind – David Brooks for the NYT