

EDITION: November 24, 2020



COVID-19 Resources

[HLB COVID-19 Resource Center](#)

Transition

HLB Article: [2020 Election Results: What Comes Next](#)

Update: As of November 23, the General Services Administration (GSA) had procedurally completed the steps in order to allow the Biden Transition team access to agency offices in order to formally begin the transition.

Biden Names COVID Taskforce and Plan

On November 9, the Biden/Harris Transition team announced its [COVID-19 Advisory Board](#) along with their [plan](#) to combat COVID-19 including strategies on testing, personal protective equipment (PPE), guidance for communities, schools and businesses, vaccine distribution, and mask mandates.

Congressional

Leadership Elections

Last week, as expected, Nancy Pelosi (D-CA) was reelected Speaker of the House, Steny Hoyer (D-MD) was reelected House Majority Leader and Jim Clyburn (D-SC) as Majority

QUALITY PAYMENT PROGRAM HIGHLIGHTS

Under federal law, Qualifying Alternative Payment Model (APM) Participant (QP) thresholds are increasing beginning on January 1, 2021. For QP status:

- The payment amount threshold is increasing from 50% in 2020 to 75% in 2021.
- The patient count threshold is increasing from 35% in 2020 to 50% in 2021.

UPCOMING HEALTH CARE ACTIVITIES ON THE HILL

There are no hearings scheduled at this time.

Whip. House Republicans also reelected their top posts with Kevin McCarthy (R-CA) as House Minority Leader, Steve Scalise (R-LA) as Minority Whip and Liz Cheney (R-WY) as GOP Conference Chair.

Similarly, the Senate also reelected their top party leaders including Mitch McConnell (R-KY) and Chuck Schumer (D-NY), who will take their posts after the January 5 Georgia runoff elections take place to determine which party will control the Senate.

Elections of Chairman and Ranking Member of House and Senate Committees will begin the week of November 30th.

Administration

Payment Rules Released

Payment rules have been delayed this year and some are still expected by the beginning of December. The following rules were recently released:

- [Advance Notice of Methodological Changes for Calendar Year \(CY\) 2022 for Medicare Advantage \(MA\) Capitation Rates and Part C and Part D Payment Policies – Part II \(Fact Sheet\)](#)
- [\(ESRD\) Prospective Payment System \(PPS\) for calendar year \(CY\) 2021 \(Fact Sheet\)](#)

Drug Pricing Rules Released

On November 20, two prescription drug pricing rules were released by the Department of Health and Human Services (HHS). The first, the Most Favored Nation (MFN) model was released as an [Interim Final Rule with Comment](#) effective January 1, 2021. The [model](#), would tie certain Medicare Part B drugs to prices in other countries. Importantly, it is a nationwide, mandatory model, that will encompass any provider/supplier that submits a claim for a separately payable Part B drug or biologic, above a de minimus threshold. The second is a [final rule](#) which will exclude drug rebates from safe harbor protections as they relate to contracts between drug manufacturers and pharmacy benefit managers (PBMs), as they relate to Medicare Part D plans. The effective date of the final rule is delayed until January 1, 2022. Both of these rules will likely face legal action by stakeholders and may be rolled back by a Biden administration. If Biden does forgo these rules, we can still expect him to pursue rulemaking on drug

pricing in his own way.

Stark and AKS Final Rules Released

On November 20, HHS released its [final rules](#) to update the [physician self-referral law](#) (referred to as the “Stark” law) regulations ([Fact Sheet](#)) and federal [anti-kickback statute](#) safe harbors for value based arrangements ([Fact Sheet](#)). The new rules are effective January 19, 2021, other than certain revisions with respect to group practices under the Stark law, which are effective January 1, 2022.

HLB will be hosting a free webinar on these rules on December 1 at 3:00pm ET. Register [here](#).

Organ Procurement Organization Final Rule Released

On November 20, CMS released its OPO [final rule](#), updating how OPOs are measured in order to hold OPOs accountable and increase performance. The [new process](#) would begin August 1, 2022 and evaluate OPOs annually with lower-ranked OPOs having four years to increase performance or face decertification or open competition for their donation service area (DSA).

Medicaid Managed Care Rule Released

On November 9, CMS released the Medicaid and Children's Health Insurance Program (CHIP) Managed Care [final rule](#). The [rule](#) is intended to reduce administrative burden and increase state flexibility and includes provisions on setting capitation rates, pass-through payments, network adequacy standards, and quality ratings. Much of the rule will go into effect beginning December 14, 2020.

Price Transparency Rule Released

On October 29, HHS released its [final rule](#) on transparency in coverage for health insurers. The [rule](#) links with the hospital rule on price transparency with the Administration's push to publish negotiated rates. The requirements would begin in 2022 with increased requirements through 2024. Although the incoming Biden Administration could make changes to the rule, it is not expected to be rescinded.

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