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Post-Election View of Potential Near-Term Federal Health Policy Agenda

The apparent election of Joe Biden as President will shift the focus and activities of the federal health policy in 2021 and for the next several years, and the ultimate outcome of the Senate races will impact those activities. HFMA has been contemplating the potential effects of the election on federal health policy. This document highlights possible changes involving federal health policy for Medicare, Medicaid, and Affordable Care Act (ACA) coverage. The approach is high level, given that the choice of the incoming HHS Secretary and CMS leadership team as well as changes in the composition of Congressional committees will also affect the evolution of policy development for these programs over the next several years. Some possible changes involve legislation while others could be accomplished administratively. In some cases, such as Medicare payment, policies are most likely to continue largely on their current track.

While not the subject of this document, dealing with the ongoing effects of the COVID-19 pandemic will undoubtedly be the top priority for action in 2021, including a broad focus on promoting economic recovery and job growth. From a health care perspective, the Biden campaign has set forth a plan that includes a new national focus on prevention, widely available testing, and support for surge capacity and treatment, along with dissemination of vaccines when available. Access to care for COVID-19 treatment and overall access to coverage for the many people who have lost their jobs and employer-based coverage is addressed, with policies involving Medicaid in particular discussed below.

Texas v. California will be decided by the Supreme Court in the first half of 2021, and that pending decision on the constitutionality of the ACA may generate legislative actions either before or after the decision. Work may resume on any unresolved issues from the 116th Congress, such as bipartisan efforts to address out of network "surprise" billing and action on prescription drug pricing.

Policies of other federal agencies affecting the health care system not addressed here may also be revisited under the new Administration. One example is Federal Trade Commission policies regarding provider consolidation, which has been a focus of research on healthcare prices.[1]

[1] See for example, COVID-19, Market Consolidation, And Price Growth, "Health Affairs Blog, August 3, 2020. DOI: 10.1377/hblog20200728.592180, https://www.healthaffairs.org/do/10.1377/hblog20200728.592180/full/.

This document identifies possible shifts in Administration priorities within Medicare, Medicaid and ACA coverage based on Biden campaign policies, recent priorities of House Democrats, a look back at the final (FY 17) Obama Administration budget submission, and in some cases from influential outside advocates and academics. The possible policies include both changes to existing systems and proposals for systemic reforms. The new Administration will have the opportunity to review regulations and demonstrations still in development. (A list of regulations in development and demonstrations that a may require action by a Biden Administration are listed in Appendices A and B.) In addition, there are some Trump Administration policies that a Biden Administration may revisit which are described in the text below.

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I. Medicare

- **Expansion of Medicare eligibility**. The Biden campaign proposed to lower the age of Medicare eligibility to 60, with the option to delay enrollment for individuals who prefer to keep employer or Exchange coverage. Federal funding for the pre-65 Medicare population would all be from general revenue. Many details are not clear, such as how the opt out of Part A would work and whether Medicare secondary payer policy would be extended to the opt-in population.

- **Medicare Benefit Structural Reforms**. Several types of Medicare benefit redesign may be considered at some point by the new Administration.
    - Parts A & B reform. Major changes to the structure of Medicare benefits could be considered, ranging from the addition of dental, hearing and vision benefits (e.g., provisions included in H.R. 3 as passed by the House in December 2019), to broader changes that have been discussed for years like combining benefits under Parts A and B and instituting an out-of-pocket cap or creating a public option for Medigap coverage. Income-related premiums could potentially be revisited; the final Obama budget would have reduced the federal subsidy to 10 percent for the highest income beneficiaries. (Currently the highest income tier receives a 15 percent subsidy.) These changes could be pursued on their own or as part of a Medicare package that addresses long-term program financing.

- Part D benefit reform. Structural reforms to the Part D benefit may also be considered. MedPAC has recommended changes to reduce the federal reinsurance subsidy to encourage plans to promote greater cost effectiveness. Under such a policy, for example, the proportion of catastrophic costs for which Part D sponsors are at risk could be increased over time while the federal reinsurance subsidy would gradually decline.

- **Medicare FFS Payment Policy.** Major changes in the direction of Medicare's FFS payment policies are not anticipated to result from the election. Policies of the current administration such as site-neutral payments, price transparency, reductions in payment for 340B acquired drugs, increasing payment for evaluation and management (E/M) services, expansion of care management services, improved payment for FDA-designated breakthrough devices and certain antimicrobial products are expected to continue to be priorities for a new administration. Unless there is Congressional action, the new Administration will face a significant reduction in the physician fee schedule conversion factor resulting in increased payments for E/M services and decreased payments for other services including radiologic and surgical procedures. The new Administration will also likely continue to align quality and payment policies across the post-acute payment systems. Flexibilities provided because of the COVID-19 public health emergency (PHE), in particular access to telehealth services (discussed further below) may be permanently extended through regulations or statutory change. The new Administration may reassess Medicare's hospital quality programs and consider consolidation of the inpatient hospital readmission reduction, hospital-acquired condition reduction, and value-based purchasing programs as recommended by MedPAC.

- **Quality Payment Program (QPP)** Several significant changes are scheduled to occur during or soon after the new Administration's first term. The MIPS adjustment percentage to a clinician's Part B professional payments reaches its statutory maximum of ± 9 percent beginning with 2022 payments (based on 2020 performance). Funding for the separate MIPS exceptional performance adjustment ends after 2024. CY 2024 will also be the final year for clinicians who meet the Qualifying APM Participant (QP) threshold to receive a 5-percent lump sum bonus. Beginning with 2026, the physician payment update, set at 0 percent through 2025, is set at 0.75 percent annually for QPs and 0.25 percent for non-QPs. The convergence of the preceding events, which are all set in statute, would rather abruptly and substantially reduce Part B reimbursement for most clinicians. Legislative action to alter one or more of the converging events is already being sought by stakeholders and their efforts are nearly certain to continue into 2021.

- **Telehealth and Remote Physiologic Monitoring**. The COVID-19 public health emergency resulted in temporary expanded access to telehealth services that have generally been very popular and created interest in making many of these changes permanent. CMS has limited authority to continue changes adopted during public health emergency on a permanent basis. For instance, the statute limits the provision of telehealth services to those that originate from health care sites in rural areas (with limited exceptions). In these situations (also with limited exceptions), the statute requires that Medicare pay the health care site from where the telehealth service originates a

facility fee ($26.65 in 2020). Broadening the telehealth benefit to allow telehealth services to originate from non-rural areas or a patient's home (other than where already allowed by statute) would require statutory change.

CMS, however, does have administrative authority to create codes for services furnished via an interactive telecommunications system outside of the statutory telehealth benefit. The agency has already taken such actions in rulemaking such as the creation of E-visits and Virtual Check-in services furnished to patients via interactive telecommunications systems. In these circumstances, CMS pays for the service under provisions of statute other than the telehealth benefit so the restrictions that the originating site be a patient care site in a rural area do not apply. Further, Medicare will not pay the telehealth facility fee in these circumstances. CMS could expand these initiatives using its rulemaking authority. For instance, CMS (or the AMA CPT) could create a code for an E/M service furnished to a patient in their home via an audio/visual interactive telecommunications system, and CMS would value that service accordingly. No statutory change would be needed, and the telehealth facility fee would not be paid, yet CMS would be able to pay for E/M services furnished to patients in their homes via an interactive telecommunications system much as it has been doing during the public health emergency.

The COVID-19 public health emergency also resulted in expanded access to remote physiologic monitoring (RPM) services that have generally been very popular and created interest in expansion for coverage of new devices used for monitoring, including the use of digital monitoring on smart phones. The new Administration will need to evaluate these products and develop policies that address whether or not they have a benefit category and are covered by Medicare.

- **Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) policies.** CMS recently issued a proposed rule (CMS-1738-P) that has implications for how CMS plans to adjust rates in various areas for DMEPOS items and services that have been included in competitive bidding and how it classifies and pay for continuous glucose monitors (CGMs) under Medicare Part B, among other issues. It is very unlikely that this proposed rule will be finalized before the end of the current Administration. A new Administration may be amenable to implementing a longer transition to fully adjusted rates in certain areas and also in making certain changes in how payment rates would be derived for CGMs to improve payment for the devices and access for beneficiaries.

- **Guarantee issue of Medigap policies.** Under Medicare, consumers who want to purchase a supplemental Medigap policy have a one-time, 6-month period when they first enroll in Medicare Part B during which they are guaranteed the ability to enroll in a Medigap policy without being subject to health-related underwriting. Outside of that period, they may be subject to premiums based on their health conditions. A new Congress may establish additional period(s) of guarantee issue for beneficiaries including for those leaving a Medicare Advantage plan. (Such a provision is included in H.R. 3.)

- **Policies to Reduce Part D Drug Costs**
  - Ceiling on out-of-pocket costs in catastrophic range. Under existing law, if a Part D enrollee's drug costs exceed a certain threshold, they enter the catastrophic phase of Part D coverage where their required coinsurance is equal to 5 percent of their drug(s) costs. Individuals needing very expensive drug treatment could reach the catastrophic region very quickly and continue to be required to making payments equal to 5 percent of very large numbers. A bipartisan proposal in both Democratic and Republican drug pricing legislation would cap a beneficiary's out-of-pocket costs. Once the cap is reached, continued coinsurance would no longer be required.[2]
  - Reduce cost sharing for generic drugs. To encourage greater use of generic drugs, a legislative proposal included in President Obama's 2017 budget could be revisited. Under the proposal, generic drug copayments would be lowered for certain low-income subsidy enrollees. To further encourage generic substitution, copayments for brand drugs for which generics are available could be increased.
  - Require manufacturers to pay a rebate. Requiring manufacturers to pay Medicare a rebate could reduce drug costs for beneficiaries and for the program overall. Senator Grassley's drug pricing legislation as well as several Democratic budget proposals have included a Part D drug rebate. One version of the Part D rebate would require manufacturers to rebate costs that exceed an amount reflecting price growth in excess of general price inflation. Some proposals would also apply a similar "inflation-based" rebate to drugs under the Part B program.[3]

- **Reconsider or Rescind Trump-era Regulations.**
  - Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary. This proposed rule modifies the Medicare coverage process to streamline coverage of devices that have FDA market authorization and breakthrough designation and have the potential to improve patient health outcomes and quality of care. Corresponding payment changes have been made to facilitate transitional pass-through payment in the outpatient setting and new technology add-on payment in the inpatient setting for these devices. It seems unlikely that a new Administration would change these policies that have been universally popular.

    This proposed rule would also codify Medicare's longstanding definition of "reasonable and necessary" that has existed only in Medicare's Program Integrity Manual. The motivation for codifying this definition to the Code of Federal Regulations (CFR) is unclear, but it could be related to the precedent set in the Allina Supreme Court decision that has resulted in CMS using notice and comment rulemaking for actions it previously would have taken through sub-regulatory procedures.

[2] An out-of-pocket cap was included in both H.R. 3 (https://www.congress.gov/116/bills/hr3/BILLS-116hr3pcs.pdf) and S. 4199, the Prescription Drug Pricing Reduction Act of 2020 (https://www.congress.gov/116/bills/s4199/BILLS-116s4199is.pdf) introduced in the 116th Congress.
[3] See S. 4199.

In addition, CMS proposes to include consideration of private insurance policies in the definition of "reasonable and necessary. As the consideration of private insurer policies is a substantive change, current practice would dictate that notice and comment rulemaking be used to adopt the new policy. Given the Allina decision, it seems more likely that codification of the reasonable and necessary definition would also continue under a new Administration. A new Administration may be more reluctant to continue or adopt (if the proposed rule is not finalized in this administration) a policy that considers private insurer coverage policies when determining Medicare coverage.

- International Pricing Model for Part B Drugs proposes a CMMI Model that will test a new way of paying for Medicare Part B Drugs. This policy never progressed beyond an advanced notice of proposed rulemaking. The key feature of the model would have used international prices as an index for determining Medicare payment for Part B drugs. Another feature of the model would have completely changed the purchasing model for Part B drugs requiring a CMS contractor to negotiate prices with drug manufacturers or distributors and requiring hospitals and physicians to purchase drugs from the contractor. The policy was modeled off of CMS' competitive acquisition program from the late 2000's that was suspended for lack of interest. However, the major difference between the competitive acquisition program and the CMMI model would have been mandated participation. This model was not popular and raised significant administrative and political issues. If the ACA in its entirety were to be declared unconstitutional by the Supreme Court (which most legal observers believe is unlikely), there would be no legal authority for this model. While a new administration may not pursue this particular idea, the Obama administration did pursue a CMMI model to control Part B drug prices, and it seems likely a new administration would also consider potential models to address the price of Part B drugs.

- **"Medicare for All" or Universal Coverage.** The new Congress may find an opportunity in the coming years to consider legislation that promotes universal coverage. A universal coverage proposal could build upon the coverage options made available through health insurance Exchanges or the Medicare program, or it could establish a new single payer entity. Existing bills include H.R. 676, the Medicare for All Act, which has been introduced in the House of Representatives in every session since 2003.[4] In the Senate, Senator Sanders has introduced a similar "Medicare for All" bill: S. 1129.

[4] S. Luthi,"Medicare for All bill loses its special number" *Modern Healthcare*, February 2, 2019, https://www.modernhealthcare.com/article/20190202/NEWS/190139976/medicare-for-all-bill-loses-its-special-number.

II. Medicaid

Proposals to continue to extend Medicaid or improve Medicaid benefits could take on greater importance in the context of the COVID-19 PHE. Many individuals have lost jobs, income, and employment-based health coverage during the pandemic. Medicaid could potentially be part of Congress' response to improving stability in the recession and providing states with additional options to extend their state program's safety net. For example, the Biden campaign's COVID-19 plan includes proposals to authorize federal matching funds for presumptive Medicaid eligibility, simplified application processes, and simplified eligibility criteria. Other Medicaid proposals that may be on the table include:

- **Incentives for Remaining States to Expand Medicaid to Low-Income Adults.** The ACA provided states with the option to extend Medicaid coverage to parents and childless adults with income below 138 percent of the federal poverty level (FPL). To date, all but 13 states have done so covering about 15 million people.[5] States were provided with enhanced federal matching funds toward the cost of their care. Beginning in 2014 and lasting for a period of 3 years, the federal government paid 100% of new enrollees' costs. The "federal share" then declined over a period to 90% where it remains today. A new Congress may consider legislation to encourage the remaining states to expand coverage. A financial incentive could be provided by renewing the 100% federal match for a transitional period for new expansion states as was proposed by President Obama in 2016. An alternative approach to improving coverage for low-income adults in states that have not chosen to expand Medicaid, included in the Biden campaign health policy platform, would be to permit adults to enroll in a public option plan premium free if they would have qualified for Medicaid had the state expanded Medicaid.

- **Extend Post-Partum Coverage for Women.** Under existing Medicaid law, states are required to cover pregnant women with income below 133% FPL for a period that extends to 60 days post-partum. Earlier in the fall, the House passed a bill to create a state plan option for states to extend Medicaid coverage for pregnant women to include 12 months post-partum instead of only 60 days.[6] If it is not enacted, it may be taken up again in a new Congress.

- **Require or Incentivize Auto-enrollment.** Each state is responsible for administering its own Medicaid program under broad federal guidelines. In establishing eligibility policies, some states have utilized auto-enrollment – that is automatically enrolling certain individuals into Medicaid based on their participation in other programs or based on computer matching. For example, some states auto-enroll individuals participating in Food Stamp programs into Medicaid. The objective is to better reach individuals who are eligible for coverage but may not know it and therefore remain uninsured. A new

[5] R. Garfield and R. Rudowitz, Eliminating the ACA: What Could it Mean for Medicaid Expansion, Kaiser Family Foundation, October 1, 2020, https://www.kff.org/policy-watch/eliminating-the-aca-what-could-it-mean-for-medicaid-expansion/.

[6] H.R. 4996, Helping Medicaid Offer Maternity Services (MOMS) Act, sponsored by Representative Robin Kelly was passed in the House of Representatives on September 29, 2020, https://www.congress.gov/116/bills/hr4996/BILLS-116hr4996rfs.pdf.

Congress may consider policies to require or encourage states to use auto-enrollment. Financial incentives could include enhanced funding for auto-enrollment matching systems. The Biden campaign's health policy platform includes a proposal to auto-enroll low income individuals when they interact with certain institutions (public schools for example) or other programs for low-income populations (such as for food stamps).

- **Continuous Eligibility for Adults with Medicaid**. A new Congress may consider ways to make Medicaid coverage more reliable for beneficiaries over the course of a year. For many low-income beneficiaries, fluctuations in monthly income mean that they lose and regain coverage often – called churning. States already have the option to provide 12 months of continuous coverage for children. A state plan option could be established permitting states to provide 12 months of continuous Medicaid eligibility for adults.

- **Glidepath for Returning to Pre-COVID Eligibility Determinations.** The Families First Coronavirus Response Act provided states with fiscal relief by increasing the federal share of Medicaid costs during the PHE. One of the conditions for receiving those the increased matching funds was that states retain eligibility at pre-PHE levels, pausing eligibility redeterminations that could result in individuals losing coverage. After the end of the PHE, if eligibility policies revert immediately to prior levels and policies, many people could lose health coverage at once. A new Congress may consider policies to prevent some or all of this immediate coverage loss; for example, enhanced funds could be gradually withdrawn from states that retain individuals beyond the end of the PHE or enrollment simplifications could be enacted to help qualify people who are eligible to retain Medicaid following the end of the PHE.

- **DSH Allotments**. Congress will likely consider further delays, and may eliminate altogether, the ACA reductions to Medicaid disproportionate share hospital (DSH) allotments. The ACA reductions to the allotments were originally to have gone into effect in 2014 but have been repeatedly delayed. They are currently scheduled to begin in December of 2021 and last through fiscal year 2025.[7] There may be bipartisan interest in additional delays or eliminating the reductions altogether especially in the current COVID-19 context where hospitals have come under the strain of reacting to the needs of COVID-19 patients while losing revenue from other sources.

- **Promoting Different Research and Demonstration Waiver Policies**. Each new administration has promoted its own priorities for Medicaid research and demonstration waivers under Section 1115 of the Social Security Act. The Obama Administration encouraged waivers to test approaches for expanding coverage to people without insurance. The Trump Administration encouraged states to impose work requirements on individuals as a condition of eligibility for Medicaid and, more recently, to establish budget caps on program spending (in exchange for other flexibilities). A Biden Administration may promote different research and demonstration waiver objectives, withdraw Trump-era waiver guidance, and revisit demonstrations to increase coverage.

[7] Most recently, the CARES Act delayed the start of the reductions from May of 2020 to a December 2021 start.

- **Rescind or Reconsider Trump-era Regulations.** CMS has yet to finalize a 2018 proposed rule, Medicaid and CHIP Managed Care, that would reduce required monitoring and oversight requirements for Medicaid managed care. The proposed rule would eliminate the oversight requirements for Medicaid managed care that were established under the Obama Administration.

III. ACA Coverage

- **Offer a Public Option.** A public option health plan could be offered alongside other insurance options available through state Exchanges. The public option plan could either be offered by the government or by private issuers but with payment rates for health care providers that are negotiated by (or capped by) the government. The expectation is that by using lower government-negotiated payment rates, a public option plan could be offered at a lower price than plans paying privately negotiated rates and could spur other issuers to lower their rates in order to better compete for enrollees with the public option. The Biden campaign supports a public option.

- **Increasing Affordability of Coverage in the Individual Market.** Increasing the affordability of individual market coverage including plans sold through health insurance Exchanges may become a priority of the new Congress. Affordability has been especially problematic for individuals who don't qualify for premium tax credits and is seen as causing lower than expected Exchange enrollment and smaller reductions in the number of people without coverage. The Trump Administration issued several regulations intended to reduce costs by increasing the availability of plans that offer fewer benefits or consumer protections.[8] The following approaches address affordability while also retaining ACA minimum benefit standards and consumer protections:

    - Increasing Premium Tax Credits for Exchange Coverage. The generosity of premium tax credits for coverage offered through Exchanges could be increased by making the credits larger for those who already qualify and by extending credits to individuals whose income is too high to qualify under existing law. The Biden campaign's health policy platform includes a proposal to eliminate the 400% income cap on tax credit eligibility and lower the limit on the cost of coverage from 9.86% of income to 8.5%. It would also increase the size of tax credits by calculating them based on the cost of a more generous gold metal-level plan, rather than a silver plan, as under existing law.
    - Re-establish Reinsurance. The ACA established two temporary premium stabilization programs: risk corridors and reinsurance -- both of which sunset after 2016.[9] Thirteen states, however, re-established reinsurance programs in their states using state innovation waivers.[10] A number of health care proposals from

[8] See section below called "Withdraw Trump-Era Regulations" for more on those regulations.
[9] A third premium stabilization program enacted by the ACA, risk adjustment, is a permanent program that remains in effect today.
[10] State innovation waivers are available under section 1332 of the ACA. They allow states to pursue innovative strategies for providing residents with access to health insurance while retaining the basic protections of the ACA.

both Republicans and Democrats offered in the 116th Congress would have established a permanent national reinsurance program making it a potentially bipartisan solution for helping to continue to lower and stabilize individual market health insurance premiums.

- **Withdraw Trump-Era Regulations.** The Trump Administration promulgated several regulations to encourage the offering of, and enrollment into, non-traditional health plans that are not subject to the ACA essential benefits rules, consumer protections, and/or premium rating requirements. The intention of the regulations was to promote lower cost coverage options. There are concerns, however, that by promoting such coverage, healthy people who need fewer protections and benefits are drawn outside of the traditional health insurance market, leaving only individuals who have increasingly high risk and escalating premiums. Two rules that could be withdrawn or reversed include a rule promoting coverage under Association Health Plans and a rule lengthening the duration that an individual may be covered by short-term limited duration plans.[11] In addition, guidance making it easier for states to encourage the offering of non-compliant plans under state innovation waivers could be withdrawn.[12]

- **Policies to Increase Enrollment.** A new Congress or Administration could enact a number of policies, not all needing legislation, to increase enrollment in individual market health plans.
    - Increase funding for navigators and outreach**.** The Trump Administration dramatically reduced funding for navigators – individuals who assist in identifying available Exchange plans and enrolling consumers in them.[13] Funding for those activities could be increased with the objective of increasing enrollment.
    - Auto-enrollment. As with Medicaid auto-enrollment, auto-enrollment policies could be established for individuals and families who are uninsured. For example, individuals who are ineligible for other sources of affordable coverage and who do not report health coverage on tax form 1095-B could be automatically enrolled in an Exchange plan.
    - Other enrollment-friendly policies. Other enrollment-friendly policies that would not require legislation include eliminating or reducing penalties for individuals who inaccurately estimate their future income for determining premium credit eligibility, lengthening open enrollment periods for individual market coverage (a proposal included in the Biden campaign's health policy platform), eliminating unnecessary verification requirements, and adding or liberalizing existing Special Enrollment Periods.

- **Other Technical Fixes.** A new Congress may consider other technical fixes to improve the availability of coverage in the individual market.

[11] Definition of "Employer" under Section 3(5) of ERISA -- Association Health Plans (83 Federal Register *(FR)* 614) and Short-Term, Limited-Duration Insurance (83 *FR* 38212).
[12] State Relief and Empowerment Waivers (83 *FR* 53575).
[13] Navigator grants in 2016 totaled $62.5 million, in 2017, $36.8 million, and in 2018, $10 million. Source: https://democrats.org/news/trump-administration-guts-funding-to-acas-navigator-program/.

- Correct the "Family Glitch." Under the ACA, if a person has coverage available through an employer and it is determined to be affordable, then he or she (and his or her family) do not qualify for a premium tax credit for an Exchange plan. Affordability is determined by comparing the cost of the employer's plan to the worker's income. The premium used for the calculation is the single worker premium instead of the family premium. As a result, a family facing an affordable single premium but an unaffordable family premium is disqualified from receiving premium tax credits for Exchange coverage. By altering the affordability formula to take into account the family premium, more families will be able to qualify for premium tax credits for Exchange coverage.
- Standardized Benefit Design. The Obama Administration proposed but never finalized a standardized benefit design for Exchange plans. The objective of standardizing plans offered through Exchanges is to make comparison shopping easier and make it more clear to a consumer when a price difference between two plans is related to additional value.

- **Action by SCOTUS on Texas v. California and legislative response.** If the Supreme Court were to rule that all or major parts of the ACA are unconstitutional without an individual mandate penalty, a new Congress may address the problem via legislation. One possible approach could be to Congress may take steps to re-establish certain coverage provisions or consumer protections – including subsidies for low-income individuals, prohibiting coverage exclusions based on pre-existing conditions, guaranteed issue, community rating, coverage for dependents to age 26, and annual limitations on cost sharing, for example. It's also possible that Congress could consider acting prior to a ruling by, for example, re-establishing a small mandate penalty or eliminating the mandate altogether.

IV. CMMI Priorities

The Centers for Medicare and Medicaid Services Innovation Center ("Innovation Center"/ "CMMI") has not figured prominently in 2020 election healthcare discussions. The only related mention is support in the Democratic Party platform to expand funding for rural healthcare demonstrations, without further details. It is unclear whether the Community Health Access and Rural Transformation (CHART) model, which has been announced but not yet started, would be canceled, revised, or continued as planned. CMMI, created by the ACA, is unlikely to face significant cuts and would be likely to benefit generally from efforts to restore and enhance the ACA. It is unclear whether the Trump Administration's recent focus on creating new and revising current models that would yield higher net savings to Medicare will be carried over to the Biden Administration. Embedding Part D costs and those for Part B drugs in model design could be a new source of potential savings and be consistent with the overall strategic policy priority of constraining drug prices. Attachment B provides information on models with proposed end dates occurring in 2020 or 2021 that could be considered for renewal by the new Administration, and models with proposed start dates in 2021 that could be considered for revision or cancellation.

V. Other Policies Affecting Private Health Insurance

- **Address Out-Of-Network Billing** Addressing out-of-network surprise billing is a bipartisan matter that was considered in the 116th Congress and is likely to arise again. It addresses concerns about unexpected bills or charges that consumers receive that they assumed would be comprehensively covered by their insurance plans. Despite early negotiations on a House and Senate bill intended to prohibit surprise out-of-network bills[14], the issue remains unresolved. Both President Trump and Former Vice President Biden have expressed support for addressing this issue.[15]
- **Health Plan Transparency**. The Trump Administration announced a final rule in November 2020 establishing broad price disclosure requirements for issuers of individual and group health insurance and group health plans. While a Biden Administration may support the objectives of increasing price transparency for consumers, the comprehensive nature of the requirements may result in some effort among health care insurers and providers to push back against the requirements. Concerns from those groups could result in some or all of the rule being reviewed before its requirements go into place beginning in 2022.

VI. Drug Pricing

The high price of prescription drugs has played a central role in Trump Administration health care policy and will likely continue to be a priority for a new Congress. Policies that may be considered include:

- **Secretarial Negotiation.** Both parties have indicated support for the Secretary of HHS to have the ability to negotiate the prices of Medicare and other drugs. In September 2020, President Trump signed an executive order providing for the Secretary to test a payment model under which Medicare drugs will be paid at no more than the lowest price paid by a member country of the Organisation for Economic Co-operation and Development.[16] H.R. 3, the drug pricing legislation favored by the current House Leadership, would have the Secretary negotiate with drug manufacturers for up to 250 Medicare drugs. The negotiated prices would be available to private payers as well. The Biden campaign includes a secretarial negotiation proposal in its health policy platform.

- **Cost and Availability of Generics and Biosimilars.** Two proposals to increase the availability of generic drugs and biologics and reduce their costs that were included in President Obama's budget proposals may be reprised. The first would prevent brand and generic drug companies from delaying the availability of new generic drugs and biologics by authorizing the Federal Trade Commission to prohibit companies from entering into

[14] K. Pollitz, et al., "An Examination of Surprise Medical Bills and Proposals to Protect Consumers from Them", Petersen KFF Health System Tracker, February 10, 2020, https://www.healthsystemtracker.org/brief/an-examination-of-surprise-medical-bills-and-proposals-to-protect-consumers-from-them-3/.
[15] See "Executive Order on an America-First Healthcare Plan" dated September 24, 2020 (https://www.whitehouse.gov/presidential-actions/executive-order-america-first-healthcare-plan/) and Biden campaign website.
[16] Executive Order on Lowering Drug Prices by Putting America First. https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/

pay-for-delay agreements between brand and generic pharmaceutical companies. The second would decrease the length of exclusivity of brand name biologics and prohibit additional periods of exclusivity for brand biologics due to formulation changes.

- **Permit Importation of Drugs.** Importing drugs from other countries at a lower price than the same drug is available in the U.S. is an approach to reducing drug costs that has had bipartisan appeal. Since it is already permitted under current law, it could be developed through administrative action. In October of 2020, the Trump Administration finalized a rule permitting states to import brand name drugs from Canada. Former Vice President Biden includes a proposal in his health policy platform to permit consumers to import prescription drugs from other countries as long as HHS certifies that they are safe.

- **Eliminate Tax Break for Direct to Consumer (DTC) Marketing.** By eliminating the ability of pharmaceutical companies to deduct spending on DTC advertising to reduce their tax liability, policy advocates hope to both increase revenues and reduce utilization of new high-cost drugs that may not be the most cost-effective solution for consumers. The Biden campaign includes this proposal in his health care policy platform.

VII. Certain Other Trump Era Regulations

- **Modernization of Stark and Anti-Kickback Laws.** In October 2019, CMS and the HHS OIG issued proposed rules designed to modernize and clarify the regulations that interpret the Physician Self-Referral Law (Stark Law) and the Federal Anti-Kickback Statute to provide greater certainty for healthcare providers participating in value-based arrangements and providing coordinated care for patients, among other changes. In August 2020, CMS extended the timeline for finalizing its rule on the Stark law regulations for an additional year citing the complexity of issues raised by stakeholders. While the HHS OIG did not announce a similar delay, it is likely the two final rules will appear at the same time because the agencies will coordinate their final policies. The Covid-19 pandemic provides ample evidence for the need to clarify and modernize these regulations to facilitate more care coordination and value-based care, and a new Biden administration will review the policies developed by the Trump administration.

- **Physician-Owned Specialty Hospitals.** Physician-owned specialty hospitals are only allowed to expand once every 2 years and must provide an opportunity for on the expansion. Any expansion is limited to 200 percent of the baseline number of operating rooms, procedure rooms and beds for which the hospital was licensed on specific dates in 2010. In the 2021 OPPS rule, CMS is proposing to allow high Medicaid physician-owned specialty hospitals to expand more frequently than once every 2 years; not to require them to provide an opportunity for public comment on the expansion and not be limited to 200 percent of the baseline number. As this policy is included in the 2021 OPPS rule that will be effective on January 1, 2021, a new Administration would have to go through notice and comment rulemaking to reimpose the expansion limit. A new Administration is unlikely to support relaxing provisions on physician-owned specialty hospitals.

- **Section 1557 Non-Discrimination Law.** In June 2020, the Trump Administration finalized rules that narrowed the scope of non-discrimination protections under regulations of the previous administration that implemented section 1557 of the Affordable Care Act. Legal challenges have prevented the Trump Administration from implementing its regulations. Section 1557 prohibits discrimination based on race, color, national origin, sex, age, and disability in health programs, and the Trump Administration rule reversed a number of protections in regulations issued by the Obama administration, including protections related to discrimination based on gender identity and sexual orientation and protections for transgender individuals, among a number of other significant limitations. The Biden campaign's health care plan includes proposals to restore the protections against discrimination based on gender, sexual orientation, gender identity and to ensure access to quality, affordable health care free from discrimination.
- **Religious Exemptions in Health Care.** The Trump administration expanded the scope of federal health care provider conscience laws to permit physicians, nurses, technicians and other providers to opt out of procedures to which they object (such as such as abortions or sex-reassignment procedures). The provider conscience rule was set aside by the courts and has not gone into effect. It is unlikely to be pursued by a Biden Administration. Similarly, the Trump Administration expanded religious and moral exemptions to the ACA's contraceptive mandate permitting employers to decline to cover contraceptives for employees or students; these rules have gone into effect notwithstanding ongoing legal challenges. A Biden Administration will likely revisit these rules to pursue its policy of ensuring access to quality, affordable health care.
- **Public Charge Rule.** The Trump Administration issued its public charge rule in August of 2019. Under law in effect since 1882, the federal government may deny a visa to anyone who is likely at any time to become a public charge; the term public charge is not defined in statute and was defined in regulation to mean anyone who would become primarily dependent on the government for subsistence. The Trump Administration public charge rule significantly expanded the standard for what constitutes a public charge to apply to anyone who would be "more likely than not" to use certain public benefits at any point in the future. The rule has been the subject of a great deal of litigation. Most recently, on November 2, 2020, a U.S district court judge declared the rule to be illegal, and challenges to that ruling can be expected. The Biden campaign policy would reverse this rule.

Attachment A. Rules Under Development

A new Administration will need to make decisions about rules that are in development. The following list includes selected HHS rules under review at OMB on November 2, 2020 and rules that have been proposed but have not yet been finalized. Annual CMS payment rules and requests for information are excluded.

Agency	Stage of Rulemaking	Title	RIN
CMS	Proposed Rule under OMB Review	Conditions for Coverage for End-Stage Renal Disease Facilities--Third Party Payments (CMS-3337-P)	0938-AT11
CMS	Proposed Rule under OMB Review	Strengthening Oversight of Accrediting Organizations (AO) and Related Provisions (CMS-3367)	0938-AT84
CMS	Proposed Rule under OMB Review	Revisions to Medicare Part A Enrollments (CMS-4194)	0938-AU27
CMS	Proposed Rule under OMB Review	International Pricing Index Model For Medicare Part B Drugs (CMS-5528-P)	0938-AT91
CMS	Final Rule under OMB Review	Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720)	0938-AT64
CMS	Final Rule under OMB Review	Medicaid and Children's Health Insurance Program (CHIP) Managed Care (CMS-2408-F)	0938-AT40
HHS/OS	Proposed Rule Issued November 2020 Not Finalized	Securing Updated and Necessary Statutory Evaluations Timely	0091-AC24
CMS	Proposed Rule Issued October 2020; Not Finalized	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) (CMS-1738-P)	0938-AU17
CMS	Proposed Rule Issued August 2020; Not Finalized	Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage (CMS-1739)	0938-AU24
CMS	Proposed Rule Issued June 2020; Not Finalized	Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value Based Payments (VBP) for Drugs Covered in Medicaid (CMS-2482)	0938-AT82
CMS	Proposed Rule Issued February 2020; Not Finalized	Preadmission Screening and Resident Review (CMS-2418)	0938-AT95
CMS	Proposed Rule Issued in February 2020; Not Finalized	Comprehensive Care for Joint Replacement Model Three-Year Extension and Modifications to Episode Definition and Pricing (CMS-5529)	0938-AU01
CMS	Proposed Rule Issued November 2019; Withdrawn	Medicaid Fiscal Accountability (CMS–2393-P)	0938-AT50

Agency	Stage of Rulemaking	Title	RIN
CMS	Proposed Rule Issued August 2019; Not Finalized	Organ Procurement Organizations (OPOs) (CMS–3380)	0938–AU02
CMS	Proposed Rule Issued July 2019; Not Finalized	Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS–3347)	0938–AT36
CMS	Proposed Rule Issued June-2019; Not Finalized	Secure Electronic Prior Authorization for Part D Drugs (CMS-4189-P)	0938-AT94
HHS/ OCR	Proposed Rule Issued June 2019; Not Finalized	Nondiscrimination in Health and Health Education Programs or Activities	0945-AA11
CMS	Proposed Rule Issued June 2018; Not Finalized	Methods for Assuring Access to Covered Medicaid Services--Rescission (CMS-2406-P)	0938-AT41

Notes: OS = Office of the Secretary; OCR = Office of Civil Rights

Sources: August 26, 2020 HHS Regulatory Agenda (85 FR 52704), March 2020 OMB Unified Agenda, Reginfo.gov website of the Office of Management and Budget.

Attachment B. CMS/CMMI Alternative Payment Models 2020

Bold font indicates an end date in CY 2020 or 2021.
Italic font indicates a start/end date change resulting from CMS responses to the COVID-19 PHE.

	2017	2018	2019	**2020**	**2021**	2022	2023	2024	2025	2026
MODEL										
Medicare Ongoing										
BPCI Advanced Model		X	X	X	X	X	X			
Comprehensive ESRD Care Model (CEC)	X	X	X	X	***X 3/31***					
Comprehensive Care for Joint Replacement (CJR) (P=Proposed extension, final rule pending	X	X	X	X	***X 9/30*** **P**	P	P			
Comprehensive Primary Care Plus Model (CPC+)										
Round 1	X	X	X	X	**X**					
Round 2		X	X	X	X	X				
Independence at Home (IAH) Demonstration	X		X	**X**	*					
Maryland Total Cost of Care Model (MD TCOC)			X	X	**X**					
Medicare Care Choices Model (MCCM)	X	X	X	X						
Medicare Diabetes Prevention Expanded Program Benefit (MDPP)		X 4/1	X	X	X	X	X	X	X	X
Medicare Track 1+ ACO Model		X	X	X	***X***					
Medicare Shared Savings Program (MSSP)	X	X	X	X	X	X	X	X	X	X
Next Generation ACO Model (NGACO/Next Gen)	X	X	X	X	***X 12/31***					
Oncology Care Model (OCM)	X	X	X	X	X 6/30	*X 6/30*				
Pennsylvania Rural Health Demonstration (PA RHD)			X	X	X	X	X	X		

	2017	2018	2019	**2020**	**2021**	2022	2023	2024	2025	2026
MODEL										
Vermont Medicare ACO Model		X	X	X	X	X 6/30	*X* *6/30*			
Medicare Start Pending	2017	2018	2019	**2020**	**2021**	2022	2023	2024	2025	
Emergency Triage, Treat, Transport Model (ET3)				X 5/1	*X* *1/1*	X	X	X	X *12/31*	
Primary Care First (PCF) General					X *1/1*	X	X	X	X	
PCF Seriously Ill Population (SIP)					X *4/1*	X	X	X	X	
Direct Contracting Model					X *4/1*	X	X	X	X	
Kidney Care Choices (Kidney Care First + Comprehensive Kidney Care Contracting)										
Cohort 1 (? = possible extension built into model)					X *4/1*	X	X	?X	?X	
Cohort 2 (? = possible extension built into model)						*X* *1/1*	*X*	*?X*	*?X*	
ESRD Treatment Choices Model (ETC)					X	X	X	X	X	
Radiation Oncology Model (RO)					X *7/1*	X	X	X	X	
Community Health Access and Rural Transformation Model (CHART)										
ACO Transformation Track						X 1/22	X	X	X	X
Community Transformation Track						X 7/22	X	X	X	X
Ongoing Medicaid / CHIP	2017	2018	2019	**2020**	**2021**	2022	2023	2024	2025	2026
Integrated Care for Kids Model (InCK)				X	X	X	X	X	X	X
Maternal Opioid Misuse Model (MOM)				X	X	X	X	X		

* Legislation was introduced in 2019 to extend the IAH demonstration (H.R.3644) or to make it a permanent program within Medicare (S. 1202).