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Health Policy Update – October 20, 2020

The Network, Specialty Provider Groups, Urge CMS to Waive Budget Neutrality in Final Physician Fee Schedule Rule

On October 5, The Network submitted comments to the Centers for Medicare & Medicaid Services (CMS) concerning the agency's CY 2021 Physician Fee Schedule (PFS) proposed rule. Among its other comments, The Network reiterated its support for CMS's Evaluation and Management (E/M) coding changes finalized last year to begin on January 1, 2021 but urged the agency to work with Congress to waive the budget neutrality adjustment for the upcoming year.
"When the E/M payment updates were finalized in the CY 2020 PFS final rule, stakeholders could not have predicted the emergence of a global health pandemic that upended the delivery of healthcare services across the country," writes The Network's Chief Medical Officer Marcus Neubauer, MD. Dr. Neubauer further warns that "layering on a 10.6% reduction to the PFS conversion factor as healthcare providers continue responding to the pandemic would add significant disruption to an already strained system."

The proposed rule's E/M coding changes have prompted numerous specialty societies and provider organizations to weigh in – most of which have expressed their support for the E/M services revaluation but cited the effects of the pandemic as a reason for CMS to either waive budget neutrally in implementing the coding changes or to delay the changes altogether.

In addition, a group of 161 bipartisan members of the House of Representatives signed a letter asking CMS to address the budget neutrality issue or hold off on implementing the coding changes. A bipartisan bill that would provide the necessary waiver authority was introduced on October 2 by Representatives Michael Burgess (R-TX) and Bobby Rush (D-IL). The bill would offset the cost of doing so by reallocating $10 billion from the HHS Public Health and Social Services Emergency Fund. This is one of multiple legislative efforts to stave off the nearly 11% cut to the 2021 PFS conversion factor. CMS is expected to issue a final rule in early December.

To view the CY 2021 PFS proposed rule, CLICK HERE.

To view The Network's comment letter, CLICK HERE.

To view the bipartisan lawmaker letter regarding the E/M payment changes, CLICK HERE.

To view the text of the Burgess-Rush bill, CLICK HERE.

The Network Outlines Concerns with Radiation Oncology Model in Letter to CMS

On October 15, The Network sent a letter to CMS Administrator Seema Verma urging the agency to delay the Radiation Oncology Model's start date and reconsider its payment methodology.

The letter noted The Network's experience in value-based care and longtime support for the development of an alternative payment model for radiation oncology. However, The Network expressed disappointment in CMS for largely ignoring stakeholder feedback and warned the Model would result in a payment cut to physician group practices beyond the 6% estimated in the final rule and provide no additional stability.

"We acknowledge the intense pressure that CMMI is under, but we feel strongly that this model was finalized on a rushed timetable during a period when providers are struggling to maintain patient access to care. Given the lack of collaboration and unwillingness to address even the most glaring omissions, we fear proceeding with the Model as currently constructed will result in a missed opportunity to advance practice transformation toward value-based care for radiation therapy," wrote The Network.

To read the letter, CLICK HERE.

To contact your Member of Congress to delay the Model's start date, CLICK HERE.

Gridlock Over COVID-19 Relief Continues, Package Unlikely Before Election Day

Though negotiations between House Speaker Nancy Pelosi and Treasury Secretary Steven Mnuchin continue, policymakers appear no closer to reaching a deal on the next package of relief to help individuals, businesses, healthcare systems and state and local governments weather the effects of the COVID-19 pandemic. And with the Senate currently occupied with Supreme Court Nominee Amy Coney Barrett's confirmation hearing, a deal appears increasingly unlikely before Election Day.

"I'd say at this point getting something done before the election and executing on that would be difficult, just given where we are in the level of details," Mnuchin said on October 13. "But we are going to try to continue to work through these issues." Speaker Pelosi set a Tuesday deadline to reach an agreement on the aid package, suggesting that Congress may not have sufficient time to pass a bill before the November 3 elections if negotiations extend beyond today.

The House passed a $2.2 trillion relief package on October 1 that included another round of $1,200 stimulus checks, extended unemployment benefits, increased provider relief funding and offered billions in additional relief for small businesses and state and local governments. The legislation also establishes a dedicated fund to support the restaurant and airline industries which have both been hit particularly hard in recent months. The new House bill is a substantial departure from the $3.4 billion package – known as the HEROS Act – that the House passed in May but is still a larger figure than what Mnuchin has said the White House would be willing to support.

Last week the White House agreed to increase its offer to $1.8 billion, up from the $1.5 billion threshold from two weeks ago. Secretary Mnuchin also stated that the White House would be open to including some aid to state and local governments – which has long been a sticking point – so long as the package includes provisions to guard against improper spending. Speaker Pelosi subsequently rejected the offer, claiming negotiations with the White House were "one step forward, two steps back." Senate Majority Leader Mitch McConnell (R-KY) later cast doubt on Republican support for a package much more than $500 billion and teed up another Senate vote on a smaller, targeted aid package this week.

To view the House's updated HEROES Act, CLICK HERE.

Amy Coney Barrett's Judiciary Confirmation Hearings

Last week, the Senate Judiciary Committee held hearings to consider the nomination of Seventh Circuit Judge Amy Coney Barrett to the Supreme Court. Judge Barrett faced key questions from lawmakers over her originalist interpretation of the Constitution as well as her views on key policy issues such as the Affordable Care Act and reproductive rights.

Democratic lawmakers repeatedly brought up President Trump's campaign promise to appoint judges to the Supreme Court who were willing to overturn the Affordable Care Act (ACA) as evidence that Judge Barrett would vote to dismantle the law but the nominee maintained that she is not "hostile" to the ACA and has not had any conversations with White House officials over how she would rule on the law. The ACA is currently subject to an ongoing legal challenge by several state Attorneys General. The Supreme Court is expected to hear oral arguments on that case on November 10th.

The Senate Judiciary Committee is expected to vote to approve Judge Barrett's nomination on October 22 with a vote on the Senate floor the following week. The vote will likely be split along party lines, though most observers expect Judge Barrett will be confirmed given the Republicans' 53-seat majority in the Senate. The nominee needs 51 votes to secure confirmation following the extension of the "nuclear option" to Supreme Court nominees in April 2017. The previous confirmation threshold was 60 votes.

To view the Judiciary Committee hearings, CLICK HERE.

Supreme Court Hears Suit Over Arkansas PBM Law

On October 6, the Supreme Court heard oral arguments in *Pharmaceutical Care Management Association (PCMA) v. Rutledge*, a lawsuit challenging a 2015 Arkansas law that regulates pharmacy benefit managers (PBMs). The law relates to maximum allowable costs and whether PBMs can reimburse pharmacies for less than the cost of dispensing a drug. The central question of the case is if state regulation of PBMs preempts, or violates federal law, namely the Employee Retirement Income Security Act of 1974 (ERISA).

The State of Arkansas has argued that the law builds on the premise of New York State Blue Cross Plans v. Travelers Insurance (1995), in which the Supreme Court ruled to permit the state regulation of drug rates as long as the legislation didn't dictate the structure of health plans. The PCMA, the PBM trade association, has disputed this claim. It holds that the law is a direct violation of ERISA because it confines plan administrators to particular choices and imposes significant regulation on appeal procedures for maximum allowable costs and other components of drug dispensing.

While the justices have yet to issue an opinion in the case, some have suggested the Court may be leaning into the arguments made by the PCMA. The line of questioning has illuminated much skepticism surrounding Arkansas's argument among the justices. Chief Justice John Roberts, in particular, seems to be skeptical of the state's claim that the law exists to regulate drug prices and not plan rules, which would violate ERISA. This is the most consequential of several PBM-related lawsuits currently working through the courts. The Supreme Court's decision will be rendered at the end of its term in June 2021.

Concerns Mount Over Administration Proposal to Issue Prescription Discount Cards

In response to a campaign promise made by President Donald Trump, officials at the White House are scrambling to deliver $200 drug discount cards to seniors by Election Day. Recent reports have indicated HHS Secretary Alex Azar and CMS Administrator Seema Verma are attempting to distance themselves from the proposal, and that both had less than one day's notice before President Trump announced it, fueling speculation whether the plan will ever be implemented.

The program, announced in September, is designed as a nationwide demonstration program that would cost Medicare approximately $8 billion. The Administration said the program would be paid for by the Medicare Part B most-favored-nation drug pricing proposal, which has yet to be detailed following President Trump's signing of an executive order directing HHS to carry out the plan on September 13. If finalized, the $200 discount cards would be distributed to 39 million Medicare beneficiaries to use at pharmacies to help lower the costs of prescription drugs—a key campaign promise of President Trump.

However, the plan has been met with significant questions and criticisms, particularly from Democratic lawmakers. On October 13, House Democratic leaders sent two letters expressing their concerns to HHS Secretary Alex Azar and U.S. Government Accountability Office (GAO) Comptroller General Gene Dodaro. The lawmakers—House Energy and Commerce Committee Chairman Frank Pallone (D-NJ), House Ways and Means Committee Chairman Richard Neal (D-MA), and Senate Finance Committee Ranking Member Ron Wyden (D-OR)—recognize that the surging cost of prescription drugs is a major problem, but highlight the dubious legal basis for the plan and question the timing so close to the election. The lawmakers demanded Secretary Azar provide more information about the plan and the statutory authority for the program and urged the GAO to conduct an expedited review of the proposal.

To read a press release about the Democratic letters, CLICK HERE.

To read the letter to HHS Secretary Alex Azar, CLICK HERE.

To read the letter to the Government Accountability Office, CLICK HERE.

Humana Achieves Significant Cost Savings Moving Doctors Off Fee-for-Service

Humana's move to value-based care has drastically lowered medical costs for seniors enrolled in Medicare Advantage plans, according to a new internal report by the insurer. Since Humana moved away from fee-for-service in favor of a value-based model, medical costs were 18.9% lower in 2019, resulting in approximately $4 billion in savings that would have been incurred had Humana Medicare Advantage members been enrolled under traditional fee-for-service agreements.

In addition to lower costs, Humana reported Medicare Advantage beneficiaries enrolled in the value-based model also saw quality of care improve. For example, seniors enrolled in Medicare Advantage that received care from doctors in value-based arrangements spent 211,000 fewer days as hospital inpatients and visited emergency departments 10.3% less than their peers enrolled in the traditional volume-based model.

Under value-based arrangements, healthcare providers are incentivized to "take a holistic view to help members achieve their best health," said Humana chief medical and corporate affairs officer Dr. William Shrank. "Central to this is the ability for value-based physicians to have access to a full and complete picture of patients' health – including their clinical, behavioral and social needs. The COVID-19 pandemic further emphasizes the need to address barriers to social isolation, food insecurity, and transportation among seniors. Addressing social determinants of health is the right thing to do and we believe helps our members spend more healthy days at home."

To read Humana's press release on the report, CLICK HERE.

To read Humana's value-based care report, CLICK HERE.

CMS Announces 2021 Medicare Highlights as Open Enrollment Begins

On October 15, CMS announced the beginning of Medicare Open Enrollment, which will run through December 7. This period allows Medicare beneficiaries to review, compare, and switch coverage. The agency also announced that since 2017, Medicare Advantage plan premiums have decreased 34% to the lowest average monthly premium since 2007. Similarly, CMS notes Medicare Part D prescription drug plan premiums have dropped 12% since 2017. Some Medicare plans also now offer a new insulin benefit in which maximum copays are set at $35 for a 30-day supply.

To read CMS' press release on the start of Open Enrollment season, CLICK HERE.

Lawmakers Solicit Recommendations for 340B Reform as Provider Groups Take Legal Action

On October 9, Senate Health, Education, Labor, and Pensions (HELP) Chairman Lamar Alexander (R-TN) and House Energy & Commerce Ranking Member Greg Walden (R-OR) asked stakeholders to share their recommendations for how to reform the 340B Drug Pricing Program, with a focus on the role of contract pharmacies as some drug makers have taken steps to limit program discounts to such entities. The duo asked stakeholders to provide their feedback by October 30.
"We are calling on all stakeholders to submit ideas on how we can improve the 340B program. Congress, as well as those that participate in the program, must be open to updating 340B so that it best serves our seniors and most vulnerable patients, while also protecting the valuable services offered by health care providers, hospitals, and clinics. Program changes are needed and long overdue, and allowing program participants to continue playing by their own rules leaves the most important 340B stakeholder on the sideline – the patient," said Alexander and Walden in a statement.

The same day, Ryan White clinics—which focus specifically on caring for low-income patients diagnosed with HIV—filed a lawsuit against the Health Resources and Services Administration (HRSA) for failing to take action against drug makers that cut off 340B discounts for drugs provided through contract pharmacies. According to the court filing, the Ryan White clinics urge the U.S. District Court for the District of Columbia to fine manufacturers that don't allow for those discounts; refund providers that were allegedly overcharged because they could not access 340B discounts through the pharmacies; set up an administrative dispute resolution process via regulation; and publicly declare that providers can receive 340B discounts through contract pharmacies.

Under a 2011 Supreme Court decision, providers have no right to sue manufacturers directly over disputes relating to the 340B drug pricing program.
To read the Alexander-Walden press release on the 340B program, CLICK HERE.

To read the court filing for the Ryan White clinics' lawsuit, CLICK HERE