Health Policy Update – November 24, 2020

The US Oncology Network Issues Statement Warning "Most Favored Nation" Model Will Disrupt Cancer Care Access

On November 23, The Network issued a statement in response to the Trump Administration's "most favored nation" (MFN) Medicare Part B drug pricing final rule. The statement notes, "The mandatory seven-year MFN model, scheduled to take effect in just over a month, without any opportunity for meaningful public comment, could fundamentally impact patient access to anti-cancer drugs while putting additional burdens on community providers."
Dr. Lucy Langer, Chair of The Network's National Policy Board stated, "Efforts to reduce drug spending are laudable but a mandatory program encompassing 100% of the country and disproportionately targeting oncology treatments is not a test, by any definition. Even more egregious, CMS' own actuaries actually predict that patients will lose access to treatment under this model."

The MFN model was announced Friday and would test paying the MFN price for the 50 highest-spend Part B drugs and biologicals. The MFN price would be phased in over time and based on international drug pricing information from 22 similar countries. In lieu of the current average sales price (ASP) +6% methodology, providers would receive a flat, per-dose add-on payment for administered drugs.

It is expected that this proposal will draw multiple legal challenges from a variety of healthcare stakeholders.

To read The Network's statement on the MFN rule, CLICK HERE.

To read the CMS press release on the MFN rule, CLICK HERE.

To read the CMS fact sheet on the MFN rule, CLICK HERE.

To read the text of the MFN rule, CLICK HERE.

Administration Finalizes Regulations in "Midnight Rulemaking" Spree

The Trump Administration moved forward with several significant regulations on Friday as it seeks finalize policies before transitioning power to President-elect Biden in January. The issuance of regulations in the so-called lame duck period between Election Day and Inauguration Day is known as midnight rulemaking.

Two significant rules impacting Medicare drug prices were finalized, including a “most favored nation” (MFN) payment model whereby Medicare Part B would test paying internationally-benchmarked prices for the 50 highest-spend drugs and biologicals. The 7-year, mandatory MFN model is scheduled to begin on January 1, 2021 and would phase in MFN prices over 4 years. Providers would be reimbursed under a two-part payment structure: a drug payment amount (MFN) and a $148.73 flat, per-dose add-on payment adjusted quarterly.

The second drug pricing rule modified existing safe harbor protections under the Anti-Kickback Statute in an effort to end rebates between pharmaceutical manufacturers and pharmacy benefit managers (PBMs). Referred to as the “rebate rule,” HHS seeks to redirect the rebate savings to patients at the pharmacy counter, estimating patients could save up to 30%. This final rule follows a July 2020 Executive Order whereby President Trump directed HHS to complete rulemaking and confirm the rule would not increase federal spending and/or patient premiums and out-of-pocket costs. HHS Secretary Alex Azar issued the requisite confirmation alongside the rule on Friday, which has been met with significant stakeholder pushback. Both drug pricing rules are expected to be challenged in court.

In addition to the drug pricing rules, CMS finalized “historic” changes to physician self-referral regulations, known as the Stark Law. The changes are intended to create permanent exceptions for value-based payment arrangements, allowing providers to enter into agreements that will improve patient quality of care and lower costs. This rule is the outgrowth of the Administration’s “Patients Over Paperwork” initiative first launched in 2017.

Finally, the Administration also finalized a rule on Friday to increase transparency and competition among organ procurement organizations (OPOs). The rule is intended to increase the supply of lifesaving organs.
To read the text of the MFN rule, CLICK HERE.

To read the text of the “rebate rule,” CLICK HERE.

To read the text of the Stark Law rule, CLICK HERE.

To read the text of the OPO rule, CLICK HERE.

Provider Groups Urge CMS to Suspend Scheduled Medicare Payment Cuts

Over the past several weeks, stakeholders in the healthcare provider community have expressed support fortwo bipartisan bills to block the Centers for Medicare & Medicaid Services from implementing payment cuts to some Medicare providers in the 2021 Physician Fee Schedule (PFS) final rule.

The scheduled payment cuts are primarily the result of increased reimbursements for evaluation and management (E/M) services beginning in 2021. Whenever Medicare payments increase for some services, the law requires those increases to be offset by payment reductions to other services. This is known as the budget neutrality adjustment. While many physicians are projected to

see payment increases under the 2021 PFS, others, particularly specialists billing lower volumes of E/M services, are projected to see net payment cuts.

To prevent these scheduled cuts from taking effect, particularly as providers are still responding to the COVID-19 pandemic, stakeholder groups have called on Congress to intervene. One bill, H.R. 8505 introduced by Representative Michael Burgess (R-TX), would waive the budget neutrality adjustment for one year. This approach is estimated to cost approximately $10 billion and would be paid for using remaining, unallocated Provider Relief Fund dollars.

Another bill, the Holding Providers Harmless from Medicare Cuts During COVID-19 Act of 2020 (H.R. 8702), introduced by Representatives Ami Bera (D-CA) and Larry Bucshon (R-IN), would effectively freeze payments at 2020 rates for services scheduled to be cut in 2021 for a period of two years. Services with reimbursement increases, including E/M services, would be implemented as scheduled. This bill is estimated to cost approximately $5-6 billion.

CMS is expected to release a 2021 PFS final rule no later than December 1, 2020. If the agency finalizes the rule as proposed, Congress must debate how and whether to address the scheduled cuts. If Congress chooses to prevent the cuts from taking effect, it will likely eye a federal funding bill that must be passed by December 11, 2020 to avoid a government shutdown.

Medical groups are also urging Congress to extend the suspension of Medicare sequestration cuts in a year-end bill. The sequestration suspension, which was enacted in March to provide financial relief amid the pandemic, is set to expire at the end of the year. A letter to Congressional leadership signed by 20 healthcare groups, including the AMA, America's Health Insurance Plans (AHIP), the Federation of American Hospitals (FAH), and the American College of Physicians (ACP), urges lawmakers to extend the moratorium for the duration of the public health emergency.

To view the text of H.R. 8505, CLICK HERE.

To view the text of H.R. 8702, CLICK HERE.

To view the letter concerning the Medicare sequester cuts, CLICK HERE.

Patient Groups Support Bill to Delay CMS Copay Coupon Rule

A group of several dozen patient and provider organizations, known as the "All Copays Count Coalition," sent a letter to Congressional leaders last week urging lawmakers to pass the Preserving Patient Savings on Drug Costs Act (H.R. 7647), a bipartisan bill that would delay a provision of CMS's 2021 Notice of Benefit and Payment Parameters final rule that allows insurers to exclude manufacturer-sponsored copay coupons from patient out-of-pocket calculations. The bill, which is sponsored in the House of Representatives by Rep. Donald McEachin (D-VA), would suspend the NBPP's expanded allowance of so-called copay accumulator programs.

The groundswell of patient support to delay this provision and pass H.R. 7647 comes as the COVID-19 pandemic reaches new heights. Patient advocacy groups contend that the copay provision harms patients with chronic illnesses who rely on expensive specialty medications to

manage their diseases. According to a recent survey by the National Hemophilia Foundation (NHF), 80% of voters believe the government should require manufacturer copay assistance to count toward patients' annual out-of-pocket limits.

Insurance industry stakeholders have defended the copay accumulator provision, arguing that drug manufacturers use coupons to avoid lowering their prices and that delaying the provision would only compound the issue of high patient healthcare costs.

To view the text of H.R. 7647, CLICK HERE.

To view the All Copays Count Coalition letter, CLICK HERE.

Study Highlights Increased Risk Faced by Cancer Patients from COVID-19 as Vaccine Manufacturers Continue to Make Progress

A recent analysis of 15 cancer studies from around the world involving more than 3,000 patients conducted by Imperial College London highlights the increased risks of severe outcomes from COVID-19 faced by cancer patients. Researchers found that cancer patients diagnosed with COVID-19 had a 23% risk of mortality compared to a 6% risk of mortality in non-cancer patients who contracted the disease.

The research shows that the risk of mortality fluctuates dramatically depending on cancer type. The risk of mortality jumps by 30% in patients with lung and blood cancer, and male patients over 65 were found to be at a higher risk for more severe consequences overall. The studies also indicated that cancer patients undergoing chemotherapy, surgery, or immunotherapy had a case fatality rate between 24% and 27.6%. The findings in these 15 studies show that cancer patients who contract COVID-19 are more likely to endure severe outcomes, implying that they are also more likely to be admitted to an intensive care unit, be hospitalized, or require ventilation. Furthermore, lung and blood cancer patients with hematologic malignancies such as myeloma, were discovered to have increased challenges recovering from COVID-19.

Though these studies illuminated similar findings across the globe – in the United States, Europe, and Asia – there is still more analysis to be conducted on the impact of cancer and cancer treatments on COVID-19 outcomes.

This news comes as the race to develop a COVID-19 vaccine continues. On November 18, Pfizer released data from its Phase III clinical trial and subsequently applied for an Emergency Use Authorization (EUA) to the FDA. The pharmaceutical company Moderna also indicated its intention to submit the same emergency use authorization application to the FDA in the coming weeks after its initial Phase III data suggested a 94.5% efficacy rate for its vaccine candidate.

To read the Imperial College analysis, CLICK HERE.

Study Finds Affordable Care Act Tied to an Increase in Early Cancer Diagnoses

On November 11, the *American Journal of Preventive Medicine*, published a new study that highlights the role of the Affordable Care Act's (ACA) Medicaid expansion with increased rates of early cancer diagnoses and decreased rates of late-stage cancer diagnoses. Collecting data from cancer registries to compare cancer diagnoses both before (2010) and after (2016) Medicaid was expanded, the researchers at the University of Pittsburgh Graduate School of Public Health found an immediate increase in early-stage cancer diagnoses within a year of ACA expansion (an increase of 21.3 per 100,000 population, or 9.14% of population), as well as a slight reduction in late-stage cancer diagnoses after three years (a decrease of 8.7 per 100,000 population, or 5.7% of population relative to the baseline).

"Medicaid expansions increased early-stage cancer diagnosis in the first year of expansion, but effects dissipated in subsequent years, suggesting a response to pent-up patient demand for screening and diagnostic services immediately after expansion," the researchers concluded. "There was also suggestive evidence of reductions in late-stage diagnosis in the third year of Medicaid expansion, highlighting the potential role of public health insurance in improving cancer outcomes among nonelderly adults. […] At a time when 28 million Americans remain uninsured, this study provides evidence that expanding insurance coverage is a potential avenue to improve cancer outcomes."

To read a press release on the study, CLICK HERE.

To read the study in its entirety, CLICK HERE.

Supreme Court Hears Arguments on Lawsuit Challenging Constitutionality of the Affordable Care Act

On November 10, the United States Supreme Court heard oral arguments in the case of *California v. Texas*, which could have major ramifications for the future of the Affordable Care Act. The central question in the case revolves around the concept of severability and whether Congress' 2017 decision to zero out the ACA's individual mandate penalty should cause the rest of the law to fall. If the law is ultimately ruled unconstitutional and struck down in its entirety, then the requirement for payers to cover Americans with preexisting conditions, including cancer, would also fall. The court is expected to rule on the case by the end of June.

Another issue the justices are considering is whether or not the 18 states bringing the suit have standing to sue. Since the individual mandate penalty was removed by Congress, the Justices seem skeptical that any harm would be incurred by the states.

Though drug pricing policy is not central to the case, it may be significantly impacted in the event that the entire ACA is struck down by the court. For example, Medicare's Part D coverage gap (often referred to as the "donut hole") that was closed by the ACA could be re-opened, causing

seniors to shoulder more out-of-pocket costs, including those for preventative services, which were also eliminated under the law.

To read the transcript of the oral arguments before the Supreme Court, CLICK HERE.