HALL RENDER'S THIS WEEK IN WASHINGTON – JULY 13, 2018

CMS RELEASES 2019 PROPOSED MEDICARE'S PHYSICIAN FEE SCHEDULE

On July 12, the Centers for Medicare & Medicaid Services ("CMS") announced numerous new policy proposals in a proposed rule to update payment policies, payment rates and quality provisions for services furnished under the Medicare Physician Fee Schedule ("PFS") for 2019. The annual update reduces payments for new drugs, streamlines evaluation and management billing codes and expands payments for telemedicine. It also seeks to broaden access to alternative physician payment programs and codify changes to the Stark Law in response to action taken by Congress. CMS characterizes the proposed rule as a significant step to ease administrative burdens on providers. Highlights of the measure include the following:

- *Evaluation and Management (E&M) Payment*. The proposed rule includes a change to simplify coding and create a single payment amount for E&M visits. CMS says this would simplify, streamline and offer flexibility in documentation requirements for these types of visits, which make up for 20 percent of allowed charges under the PFS. The proposed rule changes the current system of four sets of documentation requirements and reduces it to a single set of documentation requirements.
- *Physician Self-Referral Law.* CMS also proposes to change the Stark Law regulations to mirror action taken by Congress in the Bipartisan Budget Act of 2018 at the behest of the Hall Render Stark Law Correction Coalition. That law included provisions to codify in the statute the regulatory changes CMS made in the CY 2016 Physician Fee Schedule final rule, which include allowing a collection of documents or contemporaneous documents to meet the law's writing requirement, allowing indefinite holdovers for lease arrangements and personal service arrangements that are otherwise compliant and providing 90 days to meet the signature requirement (up from 30 days). On the recommendation of Hall Render's coalition, Congress did not limit use of the exception for temporary noncompliance with the signature requirement to the same physician/physician group once every three years. Thus, CMS has now proposed to mirror this statutory language in the regulation, eliminating any confusion about potential restrictions on the frequency of which this special rule regarding temporary noncompliance with signature requirements can be utilized. Furthermore, CMS has stated that this aspect of the rule will be effective February 9, 2018 in order to coincide with the effective date of the change established by the Bipartisan Budget Act.
- *Site-Neutral Policy*. The proposed rule retains the site-neutral policy under which certain off-campus hospital outpatient departments are paid 40 percent of what they would have received under the Hospital Outpatient Prospective Payment System.
- *Advancing Telemedicine.* The proposal would allow clinicians to be paid for virtual check-ins and for evaluating photos or videos from patients. CMS is proposing to pay for video or audio check-ins, even when they don't lead to an office visit. Historically, the agency had bundled "routine non-face-to-face communication" into payments for in-person visits. The proposed rule also allows payment for communication technology-based services and remote evaluation services furnished by rural health clinics and federally qualified health centers. Thus, the rule generally expands categories of care where telemedicine is covered and allows physicians to be paid for consultations with patients with whom they don't already have a prior relationship.

Other measures include:

- A request for information on how CMS can make health care costs more transparent
- A request for comments on how to combat opioid use disorder in Medicare
- Discontinuing functional status reporting requirements for outpatient therapy
- The proposed rule's conversion factor to calculate payment rates is $36.05, increased from the 2018 conversion factor of $35.99
- Changes to Drug Pricing under Medicare Part B

Comments are due on September 10, 2018. A fact sheet on the CY 2019 Physician Fee Schedule proposed rule can be found here.

340B CHANGES CONSIDERED BY HOUSE AND THE TRUMP ADMINISTRATION

While this week was filled with 340B activity, there is still uncertainty over how the program will be reformed. On July 11, the House Energy and Commerce Health Subcommittee held a spirited, four-hour hearing on 340B reform. The Subcommittee planned on discussing 15 different legislative measures, which included previously introduced 340B bills or discussion drafts authored by committee members, ranging from increased reporting requirements on how savings are spent to clarification of the program's intent.

At the hearing, Debra Draper, director of the health care team at the Government Accountability Office ("GAO"), discussed its recent report recommending that the Health Resources and Services Administration ("HRSA") take additional steps to ensure contract pharmacies comply with 340B program requirements. The Subcommittee also heard testimony from industry leaders who united around the need for greater accountability but warned against measures that would restrict patient access to affordable drugs. Charles Daniels, pharmacist-in-chief and associate dean at the University of California, San Diego, stressed that cuts to the 340B program would negatively affect his health system's ability to serve indigent patients.

Although the hearing was contentious at times, there was bipartisan agreement among members over clarifying the program's intent, laying out well-defined eligibility regulations and eliminating the risk of duplicate discounts through Medicaid's drug rebate program. Even though there appears to be significant momentum in the House for 340B reform, it is still unlikely that a legislative measure can get the 60 votes needed to pass the Senate.

Meanwhile, at the annual meeting of 340B Health, Department of Health and Human Services Secretary Alex Azar indicated that his organization is also considering changes to the 340B program. Azar stressed the need for increased oversight and transparency but offered few details on specific changes being considered. The Secretary's remarks were in line with the administration's policy objectives released earlier in the year, which include increasing competition in the drug market, promoting negotiations between pharmaceutical companies and the government and creating incentives to lower list prices to decrease out-of-pocket costs. Azar also specified that the rule to set ceiling prices for drug manufacturers in the 340B program, which allows hospitals to know if they are being overcharged, will be coming soon.

Finally, rumors are circulating in Washington that CMS will propose new cuts of nearly 30 percent to Medicare Part B drug payments made to 340B hospital outpatient facilities offsite. This move would be similar to the cuts that took effect in January, but were limited to locations physically connected to participating hospitals, and expand the number of 340B health facilities that will be affected by payment cuts for all physician-administered drugs.

HOUSE WAYS AND MEANS COMMITTEE ADVANCES HEALTH BILLS

On July 12, the House Ways and Means Committee approved 11 health care bills that would change the rules on tax-favored health savings accounts, retroactively amend the Affordable Care Act's employer mandate, delay the Cadillac tax until 2023 and allow consumers to use tax credits to purchase off-exchange products. The Joint Committee on Taxation projects the bills will cost about $92 billion. Ways and Means Committee Chairman Kevin Brady (R-TX) expects the measures to be introduced on the House floor as a package before the August recess. Some of the measures passed by the committee include the following:

- H.R. 4616 would retroactively strike the tax penalty for not complying with the Affordable Care Act employer mandate for 2015 through 2018 and delay the Cadillac tax on high-cost employer coverage until 2023.
- H.R. 6199 would amend the Affordable Care Act to make some over-the-counter medical products a qualified expense for HSAs and FSA without prescription.
- H.R. 6312 would authorize patients to spend up to $1,000 of pre-tax account dollars to purchase gym memberships, fitness classes or exercise safety equipment.
- H.R. 6301, H.R. 6317 and H.R. 6305 would expand the ways patients can use Health Savings Accounts.
- H.R. 6309 would permit working seniors eligible for Medicare Part A to contribute to a Health Savings Account.
- H.R. 6314 would allow catastrophic health plans to be paired with a Health Savings Account.
- H.R. 6311 would permit people to use refundable, but not advanceable, premium tax credits to purchase coverage off-exchange and would let any consumer use their tax credits to purchase a catastrophic plan.

- H.R. 6306 would increase the annual HAS contribution limits to match the sum of the qualifying health plan's minimum annual deductible and the allowable out-of-pocket costs.
- H.R. 6313 would permit flexible spending account funds to roll over from year to year.

HEALTH-RELATED BILLS INTRODUCED THIS WEEK

Rep. Bill Huizenga (R-MI) introduced H.R. 6343 to provide for a demonstration program and pilot project to expand choice for inpatient psychiatric services under Medicaid and Medicare.

Rep. Jacky Rosen (D-NV) introduced H.R. 6340, the Capping Prescription Costs Act of 2018.

Sen. Elizabeth Warren (D-MA) introduced S. 3194 to amend the Patient Protection and Affordable Care Act to cap prescription drug cost-sharing.

Rep. Michael Burgess (R-TX) introduced H.R. 6314, the Health Savings Act of 2018, to amend the Internal Revenue Code of 1986 to allow bronze and catastrophic plans in connection with health savings accounts.

NEXT WEEK IN WASHINGTON

Congress is back for a full legislative week. Congressional committees have targeted Tuesday, July 17 as a day for health care policy hearings. The House Ways and Means Health Subcommittee will hold a hearing on modernizing the Stark Law, which Subcommittee Chairman Peter Roskam (R-IL) called a first step to “aligning current law with current expectations.” The hearing will also examine the Administration's effort to change the Stark Law.

The Senate, Health, Education, Labor and Pensions ("HELP") Committee will hold a hearing on reducing health care costs. The House Energy and Commerce Oversight and Investigations Subcommittee will also hold a hearing on health care costs. The House Ways and Means Oversight Subcommittee will hold a hearing on Medicare fraud. On July 19, the House Energy and Commerce subcommittee will hold a hearing on "21st Century Cures Implementation: Examining Mental Health Initiatives."

THIS WEEK IN WASHINGTON IN HISTORY

1850, 168 years ago this week, Millard Fillmore was sworn in as president after President Taylor died the day before.

1995, 23 years ago this week, President Clinton reestablishes diplomatic relations with Vietnam while being advised by Senator John McCain who was a prisoner of war in Vietnam for five years.

For more information, please contact:

- John Williams III at (202) 370-9585 or jwilliams@hallrender.com;
- Andrew Coats at (202) 370-9587 or acoats@hallrender.com;
- Abby Kaericher at (202) 780-2989 or akaericher@hallrender.com; or
- Your regular Hall Render attorney.