Tuesday, February 11, 2020

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Insurer Groups, CMS Announce Efforts Aimed at Improving Prior Authorization

In January, America's Health Insurance Plans (AHIP), along with several of its members, announced that it will launch the Fast Prior Authorization Technology Highway (Fast PATH) initiative in an effort to automate and speed prior authorization review and approval. **Read below.**

FULL STORIES

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On February 7, an opinion editorial penned by Debra Patt, MD was published in *Morning Consult* calling on HHS and CMS to prohibit step therapy practices for Medicare Part B drugs.

Dr. Patt, a medical oncologist with Texas Oncology and chair of the breast cancer subsection of the pathways task force for The US Oncology Network, details how a new Medicare Advantage policy known as step therapy allows insurers to overrule physicians' prescribing decisions – forcing patients to begin with insurer-preferred therapies even when providers doubt efficacy or the patient has previously tried the same therapy while covered by a different insurance plan. Dr. Patt argues permitting step therapy for Part B drugs covered by Medicare Advantage plans puts patient care at risk.

To read Dr. Patt's column, CLICK HERE.

President Renews Call for Drug Pricing Reform, Highlights Other Healthcare Issues in State of The Union

On February 4, the President delivered his third official State of The Union address which featured a number of the administration's healthcare priorities and urged Congressional action on drug pricing. The President called on lawmakers to enact a bipartisan drug pricing bill, announcing that he would sign it "into law without delay," though he stopped short of explicitly endorsing the Senate Finance Committee legislation advanced by Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) last year.

Noticeably absent from the address was any mention of the much-anticipated International Pricing Index (IPI) Demonstration Model first proposed in 2018, which aims to tie American drug prices to prices paid in other developed countries.

Other healthcare topics mentioned in the President's address included touting the Center for Medicare & Medicaid Services' recent healthcare price transparency rules, the expansion of short-term and association health plans, and a reiteration that the administration would protect people with preexisting conditions should the Affordable Care Act be struck down in federal court.

To read the full transcript of the State of The Union Address, CLICK HERE.

Administration Unveils 2021 Budget Proposal

On February 10, the administration released its $4.8 trillion budget plan for Fiscal Year (FY) 2021, which aims to eliminate the federal deficit within 15 years. The proposal would reduce federal spending at the Department of Health and Human Services (HHS) by 9 percent relative to current law. HHS Secretary Alex Azar will testify before the Senate Finance Committee this week to discuss the proposed budget.

Over the next 10 years, the budget proposes $920 billion in gross Medicaid savings and $756 billion in gross Medicare savings. As in the FY20 President's Budget, the FY21 Budget would pay all off-campus hospitals outpatient departments (HOPDs) at the physician office rate (a savings of $47.2 billion over 10 years) and pay on-campus HOPDs at the physician rate for certain services (savings of $117.2 billion over 10 years). Unlike last year, the administration is proposing an exemption to the on-campus HOPD proposal for rural hospitals.

In lieu of a detailed drug pricing proposal, the budget includes a $135 billion savings allowance to accommodate "legislative efforts" to drive down prices. The administration notes its support for establishing an out-of-pocket maximum under Part D and changes to lower generic and biosimilar drug costs.

The budget request also includes $38.7 billion for the National Institutes of Health and $6.2 billion for the Food and Drug Administration.

The President's budget is largely a vision document used to highlight the administration's policy areas of interest and would require additional regulations or legislation before being enacted.

To view the government-wide President's budget, CLICK HERE.

To view the HHS Budget in Brief, CLICK HERE.

To view a fact sheet on the Health and Wellness provisions, CLICK HERE.

Lawmakers Introduce Bill to Increase CMMI Transparency

On February 3, Representatives Terri Sewell (D-AL), Adrian Smith (R-NE), Tony Cárdenas (D-CA) and John Shimkus (R-IL) introduced a bipartisan bill aimed at increasing transparency and accountability within the Center for Medicare and Medicaid Innovation (CMMI). Titled "The Strengthening Innovation in Medicare and Medicaid Act,", H.R. 5741 would require the Department of Health and Human Services to mitigate any adverse patient impact stemming from CMMI demonstration models.

The bill limits the scope of CMMI models, stipulating length cannot exceed 5 years and limiting participation to no more individuals than necessary to obtain a statistically valid sample. It also creates a hardship exemption process, creates an expedited Congressional disapproval process, and standardizes the rulemaking process.

To read the bill, CLICK HERE

Ways and Means Health Subcommittee Holds Hearing on Drug Pricing

On February 5, the House Ways and Means Health Subcommittee held a hearing to discuss prescription drug pricing. Titled “More Cures for More Patients: Overcoming Pharmaceutical Barriers,” the hearing featured the following witnesses:

- Juliana Keeping, Patient Advocate, Mother to a Child with Cystic Fibrosis;
- Brad W. Sester, Senior Fellow for International Economics, Council on Foreign Relations;
- Ge Bai, PhD, CPA., Associate Professor of Accounting, Johns Hopkins Carey Business School;
- Aaron S. Kesselheim, MD, JD, MPH, Professor of Medicine, Harvard Medical School/Brigham and Women’s Hospital, and;
- Tara O’Neill Hayes, Director of Human Welfare Policy, American Action Forum.

Witnesses discussed the challenges rising drug costs pose to patients and families, the impact on the federal budget and continued research and development, and how tax policy may incentivize drug companies to shift profits overseas. Subcommittee members continued to disagree on the best course of action. Democrats lauded H.R. 3, which would allow the government to negotiate drug prices and tax drug manufacturers who refuse to participate; Republicans argued H.R. 3 would discourage innovation and expressed support for Medicare Part D redesign instead.

To read more about the hearing, including witness testimony, CLICK HERE.

CMS Enables States to Restructure Medicaid Program Benefits

On January 30, the Centers for Medicare & Medicaid Services unveiled the “Healthy Adult Opportunity” initiative, enabling states to substantially restructure their Medicaid programs through a block grant or per capita financing arrangement. The initiative is primarily targeted at states who expanded Medicaid under the Affordable Care Act; only non-elderly adults without dependents would be eligible – beneficiaries made Medicaid-eligible on the basis of disability, pregnancy, or receiving long-term services and supports could not participate.

The voluntary program aims to give states flexibility regarding benefits, coverage, cost sharing, and oversight. Permitted changes include modifying prescription drug formularies, adjusting cost sharing requirements to incentivize high value care, and waiving retroactive coverage and hospital presumptive eligibility requirements.

The new initiative has been met with criticism from lawmakers and advocates who say it undermines the Medicaid program -- a critical component of the social safety net. CMS claims the program is necessary to ensure Medicaid’s long-term financial sustainability

by letting states operate with a defined budget. On Thursday, February 6, the House of Representatives voted 223-190 on a non-binding resolution to disapprove of the administration's HOA initiative.

To view a CMS fact sheet on the Healthy Adult Opportunities initiative, CLICK HERE

CMS Clarifies Use of Copay Accumulators

On January 31, the Centers for Medicare & Medicaid Services (CMS) issued the proposed annual Notice of Benefit and Payment Parameters Rule for 2021, also known as the Proposed 2021 Payment Notice. The proposed NBPP would allow, but not require, copay accumulators for all commercial plans, including self-insured and insured individual and group plans. Under the proposal, HHS would allow plans to not count the value of drug manufacturer copay coupons towards both beneficiary deductibles and out-of- pocket limits. State laws limiting copay accumulators will still apply to insured plans; currently four states have those laws in place (AZ, IL, VA, and WV).

Previously, the 2020 NBPP adopted changes allowing plans to exclude manufacturer copay coupons from a member's maximum out-of-pocket if medically appropriate generic equivalents were available, but several months after the rule was issued, CMS issued new guidance to delay enforcement due to stakeholder concern and confusion.

"We encourage issuers and group health plans to consider utilizing this proposed flexibility to find innovative methods to address the market distortion that occurs when consumers select a higher-cost brand name drug when an equally effective, medically appropriate generic drug is available," CMS said in the rule.

To read a press release from CMS about the proposed rule, CLICK HERE.

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

FDA, FTC Outline Steps to Deter Anticompetitive Practices in Biosimilar/Biologic Advertising

On February 3, the United States Food & Drug Administration (FDA) and the Federal Trade Commission (FTC) released a joint statement outlining a plan to coordinate efforts to deter anti-competitive business practices and support a competitive market for biological products, including the adoption of biosimilars and interchangeable products. The joint statement describes key steps the agencies will take to address false or misleading promotion about biosimilars within their respective authorities and deter anti-competitive behavior.

Joint efforts between the FDA and FTC include collaborating on public outreach efforts with stakeholders, hosting public workshops on creating a competitive market for biosimilars, publishing draft guidance regarding how to present data, and exchanging information about best practices.

To read the joint statement of the Food & Drug Administration and the Federal Trade Commission, CLICK HERE.

To read the FDA-FTC press release on the joint statement, CLICK HERE.

CMS Expands Coverage of Next Generation Sequencing Diagnostic Tests

On January 27, the Centers for Medicare & Medicaid Services (CMS) announced that it would expand coverage of FDA-approved laboratory diagnostic tests that use Next Generation Sequencing (NGS) for patients with germline, or inherited, ovarian or breast cancer. In addition, CMS gave Medicare Administrative Contractors discretion to determine coverage of NGS laboratory tests for other inherited cancers, which is expected to reduce mortality and improve health outcomes.

The announcement marks the most significant increase in the number of Medicare beneficiaries who will have access to NGS in managing inherited cancers since Medicare first began covering laboratory diagnostic tests using NGS in March 2018.

To read CMS' full decision memo on this policy, CLICK HERE.

To read the CMS' press release on this policy, CLICK HERE.

Insurer Groups, CMS Announce Efforts Aimed at Improving Prior Authorization

On January 6, America's Health Insurance Plans (AHIP), along with several of its members, announced that it will launch the Fast Prior Authorization Technology Highway (Fast PATH) initiative in an effort to automate and speed prior authorization review and approval. The groups, who cover approximately 60 million Americans, will launch the initiative in March or early April. Fast PATH aims to expedite the prior authorization for drug dispensing and surgical procedures using automated technologies.

AHIP's move comes as the Centers for Medicare & Medicaid Services (CMS) announced it is developing a Documentation Requirement Lookup Service (DRLS) based on feedback from thousands of stakeholders. DRLS will make it easier for clinicians to understand whether a drug or procedure requires prior authorization at the point of care. While CMS will create an electronic resource to streamline the process, policymakers recognize the need to continue to implement non-electronic solutions as well.

To read more about AHIP's Fast PATH program, CLICK HERE.

To read more about CMS' Documentation Requirement Lookup Service (DRLS), CLICK HERE.