

### HHS EXTENDS PUBLIC HEALTH EMERGENCY. PRICE TRANSPARENCY RULING, COVID **GUIDANCE & CLARIFICATIONS, NEW** VALUE-BASED DRUG PRICING PROPOSAL **RELEASED**

While the business climate remains unsettled, there continues to be important regulatory activities and court rulings affecting companies involved in the selfinsurance marketplace plans, which SIIA's government relations team remains heavily involved in impacting and tracking. Watch for additional real time updates in the coming months as developments warrant. Should you have questions or would like to discuss these, or other policy or regulatory issues, please contact Ryan Work (rwork@siia.org) or Chris Condeluci (ccondeluci@siia.org).

# HHS TO EXTEND PUBLIC HEALTH EMERGENCY

The U.S. Department of Health & Human Services (HHS) recently indicated that the agency intends to extend the current COVID-19 Public Health Emergency Declaration, currently set to expire on July 25th, for an additional 90 days.

A number of policy and regulatory mandates and guidelines are based on the public health emergency deadline, including COVID-19 testing cost-sharing requirements and the waivers surrounding telehealth. It is important to note that the Public Health Emergency Declaration is not the same as the National Emergency Declaration, which was implemented on March 13th by the President, and which other regulatory changes, such as the COBRA extension deadlines, are based upon.

# HOSPITAL PRICE TRANSPARENCY COURT RULING

On June 23rd, a federal court ruled in favor of upholding the U.S. Department of Health and Human Services' (HHS's) final rule issued last November that would require hospitals to publicly disclose "standard charges" for items and services they provide, in addition to the negotiated prices of up to 300 "shoppable" medical services.

The final rule is set to take effect in 2021. This rule was challenged by the American Hospital Association (AHA), who has sought to rescind the rule before it took full effect. The judge disagreed with the AHA's argument of

First Amendment protections for medical prices, as well as against the argument that revealing such prices would have a chilling effect on negotiations between payors and providers.

The judge stated that the final rule was reasonably related to the government's interest in lowering healthcare costs and giving consumers more pricing data to help them decide on medical treatments. The AHA is expected to file an appeal and ask for an expedited ruling.

The full ruling may be found here.

#### GROUP HEALTH PLAN TRANSPARENCY RULE EXPECTED THIS FALL

Earlier this year, HHS issued proposed regulations requiring both fully-insured and self-insured "group health plans" to publicly disclose the plan's negotiated in-network rates and out-of-network payments, along with a participant's cost-sharing liability for specific medical items and services.

While SIIA fully supports increasing the transparency we are also on record citing a number of concerns related to the difficulty that self-insured plans may have complying and accessing the various data and cost requests.

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#### Inside the Beltway

Most recently, SIIA members were able to speak directly with HHS officials explaining these difficulties and suggesting possible ways of resolving the issues of concern. We expect the proposed rules will be finalized sometime in the Fall.

#### CMS ISSUES COVID-RELATED FAQS & CLARIFICATIONS

On June 23rd, the Centers for Medicare & Medicaid Services (CMS) issued a Frequently Asked Questions (FAQs) document related to the implementation of the requirements set forth in the recently enacted Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Among other things, the FAQs flesh out the types of FDA-approved and non-FDA-approved COVID tests that must be covered by an insurance carrier or self-insured plan sponsor with no cost-sharing.

The FAQs also clarify that at-home COVID tests must be paid for by the carrier or plan sponsor on a first-dollar basis if it is deemed medically appropriate by a licensed provider. Importantly, the FAQs explain that if an employer requires an employee to take a COVID test before returning to work, this test is not considered medically appropriate, and thus, the carrier or plan sponsor is not required to pay for the test on a first-dollar basis (i.e., cost-sharing can be applied).

CMS justified this conclusion by re-stating that COVID testing must be free if the test is recommended by a licensed medical provider as being medically appropriate, and CMS noted that a test required as part of a "return to work" program does not meet this standard.

One important clarification to note is that HHS underscores the daily monetary penalty for health care providers if they refuse to post publicly available cash prices

for COVID testing under the CARES Act mandate.

Under this mandate, provider payments for COVID testing must be at an innetwork or negotiated rates and, if none exist, similar to the cash price made available by the provider.

The FAQs also include a telehealthrelated question, confirming that an employer can offer telehealth services to employees who are not other otherwise eligible to enroll in the employer's group health plan. Interestingly, this temporary rule is only available to large employers.

The full FAQ document can be found here.

## CMS PROPOSED RULE ON VALUE-BASED DRUG PRICING

On June 17th, CMS issued a proposed rule governing value-based payment under Medicaid for high-costs prescription drugs, such as gene therapy, based on clinical outcome.

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#### Inside the Beltway

According to CMS, this is the first update to the payment model in nearly 30 years and seeks to create more innovation in payment models and reduce health care spend. Although the proposed rule is limited to Medicaid programs, this will no doubt impact the private market and selfinsured plans.

In short, CMS's proposed rule gives states more flexibility to enter into valuebased purchasing agreements with drugmakers for new and high cost drugs and would make changes to the calculation of the average manufacturer price of a brand-name drug that has an authorized generic.

In order to encourage value-based purchasing arrangements, the rule would ease certain reporting requirements for drug manufacturers surrounding the average manufacturer price.

For example, a drug manufacturer could report multiple best prices for a therapy drug, but tie that to a value-based purchasing agreement. Other important provisions to note are a proposed change in the definition of performance requirements under bundled sales so value-based arrangements can be utilized, and changes to the calculation of the average manufacturer price for a brand-name product to exclude the sales of authorized generic drugs made by the original manufacturer.

#### CMS FACT SHEET

The full proposed rule can be found here

If you have questions or would like to discusses these or other issues in more detail, please contact Ryan Work (rwork@siia.org) or Chris Condeluci (ccondeluci@siia.org).

