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ACTION REQUESTED: Review 340B Final Payment Remedy Estimates by 11/30

On Nov. 8, the Centers for Medicare & Medicaid Services (CMS) finalized a remedy for the 340B-acquired drug payment policy for calendar years 2018-2022. An IHA summary of the proposed payment remedy is [here](#). Hospital-specific repayment amounts were calculated by CMS and can be found in [Addendum AAA](#).

IHA prepared facility-specific financial impact reports assessing the estimated impact of this payment remedy for your facility. We encourage all hospitals paid under the Outpatient Prospective Payment System to review these estimates as soon as possible. To review your hospital's report, log in as a member to the IHA C-Suite. This can be found on IHA's [website](#).

Anticipating potential errors in the final rule, CMS established a technical correction process for 340B hospitals to request corrections to any errors identified in CMS' calculation of remedy payments. 340B hospitals can alert CMS to potential errors in the calculation of their final lump sum repayment amount in Addendum AAA by emailing CMS at outpatientpps340b@cms.hhs.gov by 10:50 p.m. CT this Thursday, Nov. 30.

[Contact us](#) with questions.

State Launches CADC Workforce Expansion Program

The Illinois Certification Board (ICB) and the Illinois Dept. of Human Services Division of Substance Use Prevention and Recovery (IDHS/SUPR) have launched a new workforce incentive program for certified alcohol and other drug counselors (CADCs) in Illinois. Under the CADC Workforce Expansion Program, individuals in an ICB Accredited Training Program wishing to enter the substance use services field in Illinois can receive tuition payments, scholarships, internship stipends and certification-related payments to obtain their CADC credential.

The program will also help with job placement, credential renewal, continuing education, and other incentives to reduce barriers to education and workforce participation. To be eligible for the program, individuals must pursue a CADC credential and agree to a two-year employment period within an SUPR-licensed/SUPR-funded prevention, treatment, harm-reduction or recovery organization.

For more information on the CADC Workforce Expansion Program, including application information, [click here](#).

Federal Action Seeks to Strengthen American Supply Chain

Yesterday, as part of an ongoing national effort to strengthen the American supply chain, the White House announced plans to give the U.S. Dept. of Health and Human Services (HHS) broader authority under Title III of the Defense Production Act to invest in domestic manufacturing of essential medicines and medical countermeasures. Of note, HHS will invest \$35 million in domestic production of key starting materials for sterile injectable medicines. The Department will also designate a new Supply Chain

Resilience and Shortage Coordinator, who will lead efforts to strengthen supply chain resilience and address related shortages. Additionally, the Administration said the U.S. Dept. of Defense will soon release a report on pharmaceutical supply chain resilience aimed at reducing reliance on high-risk foreign suppliers.

Telehealth Providers: HHS Issues HIPAA Best Practices

Recognizing the evolving landscape of care delivery and growth of telehealth, the U.S. Dept. of Health and Human Services (HHS) published a [resource guide](#) aimed at assisting telehealth providers in explaining, in plain language, the privacy and security risks to patients who engage in telehealth. The guide explains the risks in telehealth visits and ways to reduce these risks. Importantly, the guidance makes clear healthcare providers are not required by Health Insurance Portability and Accountability Act of 1996 (HIPAA) to provide this education. However, the goal is that the resource guide will help providers who would like to discuss potential risks with the patient.

CLASS I RECALLS: Drug Vials, Infusion Pump Systems

The Food and Drug Administration (FDA) [has identified](#) the recall of 10,655 Infusomat Space Volumetric Infusion Pump Systems by B. Braun Medical as a Class I recall due to the potential for serious injury or death. The pumps are used by trained healthcare professionals in healthcare facilities for use on adults, pediatrics and newborns for the intermittent or continuous delivery of parenteral fluids, medications, blood and blood products. The pump systems have been recalled due to faulty occlusion alarms, which may sound when no occlusion exists, causing the pump to stop medication delivery. Interruption to the infusion of high-risk medications may require medical intervention to prevent permanent impairment to body structures or body functions. In some cases, this may be life-threatening or may lead to death. There have been 51 complaints, one reported injury and one death related to this recall.

The FDA [also reports](#) that Exela Pharma Sciences is recalling more than 415,000 drug vials as part of a Class I recall due to the possible presence of silicone. The three products impacted are 8.4% sodium bicarbonate injection, used to treat metabolic acidosis; midazolam in 0.8% sodium chloride injection, used for sedation; and ELCYS (cysteine hydrochloride injection), used for nutritional requirements per total parenteral nutrition. [According to](#) the FDA, the medications were pulled following a routine inspection that found silicone in samples.

COVID-19 Information

Since the end of the COVID-19 Public Health Emergency on May 11, the Illinois Dept. of Public Health (IDPH) is releasing updated COVID-19 data every other week. [Click here](#) for the most recent hospitalization update. IDPH will continue to report the weekly number of people with COVID-19 admitted to hospitals from emergency departments, deaths and vaccinations, as well through the dashboard of the [Illinois Wastewater Surveillance System](#).

Briefly Noted

Yesterday, the Food and Drug Administration [approved](#) Ogsiveo (nirogacestat) tablets, the first therapy for adult patients with progressing desmoid tumors. These rare, non-cancerous tumors may invade into surrounding structures and organs, resulting in pain, issues with being able to move and decreased quality of life. Although surgical removal has historically been the treatment of choice, there is a high risk that the tumor will return or that other health challenges will occur after removal; therefore, systemic therapies (cancer treatment targeting the entire body) are being increasingly evaluated in clinical trials.

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