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Congress is in recess for a district work period and will return on October 15 after the Columbus Day holiday.

Surprise Billing

Please continue to reach out to your federal legislators about surprise billing during the recess as the issue will be on the front burner when Congress returns. We continue to reaffirm ACEP's intent to work with Congress on behalf of all emergency physicians to find a federal solution to protect patients from out-of-network surprise billing that will avoid any unintended consequences to the broader health care system. We continue to seek co-sponsors for ACEP's preferred legislative vehicle, H.R. 3502, introduced by Reps. Ruiz, MD (D-CA) and Phil Roe, MD (R-TN) and have been doing public social media thank yous to all of the co-sponsors of the bill. To see if your member of congress is a co-sponsor, please [click here](#). Please reach out to thank your legislator or send another request if he/she is not on the list by accessing this [link to our action site](#) where you can send an editable email. Our message continues to emphasize the need for an independent dispute resolution (IDR) like the mechanism included in H.R. 3502, and to build the co-sponsor list of the bill to point to support for IDR among members of the House.

Congress Urges FDA to Release Drug Shortages Task Force Report

Last week, Reps. Brett Guthrie (R-KY) and Eliot Engel (D-NY), along with 92 other bi-partisan lawmakers, sent a [letter](#) to Acting FDA Commissioner Dr. Ned Sharpless urging the agency to prioritize the release of the interagency Drug Shortages Task Force report. As you may recall, the Drug Shortages Task Force was created last year at the behest of ACEP who worked with Reps. Guthrie and Mike Doyle (D-PA) to obtain more than 100 bi-partisan signatures on a letter to then-FDA Commissioner Scott Gottlieb encouraging him to work with stakeholders to identify solutions to the drug shortages problem. ACEP and other interested parties participated in discussions with the FDA, but we have been awaiting the release of the report.

House Committee Discusses Prescription Drug Prices

On Wednesday, the House Energy and Commerce Health Subcommittee held a hearing on prescription drug prices. The legislative solutions discussed by lawmakers included the recently released bill, the "Lower Drug Costs Now Act" (H.R. 3), introduced by Reps. Frank Pallone (D-NJ), Richie Neal (D-MA), and Bobby Scott (D-VA), which would establish a fair price negotiation program that would allow the Secretary of HHS to negotiate directly with drug manufacturers for the prices of certain drugs that lack competition. The Secretary would identify and publish a list of 250

negotiation-eligible brand drugs with the greatest total cost to Medicare and the U.S. health system, based on data to determine aggregate costs. From these 250 negotiation-eligible drugs, the Secretary would select at least 25 drugs to be subject to negotiation. For each of these selected drugs, the Secretary would enter into an agreement with the manufacturer in order to begin a voluntary negotiation process. Insulin products would also be subject to negotiation, in addition to the other selected drugs. H.R. 3 establishes an upper limit for the price reached in any negotiation as no more than 1.2 times (or 120 percent) of the volume-weighted average price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the average international market (AIM) price.

In addition, H.R. 3 would establish a mandatory rebate for drug manufacturers of all covered Part B and Part D drugs that increase in price faster than inflation. A Part B rebatable drug is defined as a drug or biological paid for under Medicare Part B, excluding certain vaccines and drugs that have average total allowed charges for a year per individual of less than \$100. The bill would also make changes to the structure of the standard benefit design for Medicare Part D and create an out-of-pocket maximum for Part D enrollees.

Other legislation under consideration by the Committee include H.R. 275, the "Medicare Prescription Drug Price Negotiation Act," sponsored by Reps. Peter Welch (D-VT) and Francis Rooney (R-FL), which would give the Secretary of HHS authority to negotiate the prices, including discounts, rebates, and other price concessions, that may be charged to prescription drug plans (PDPs) for covered Part D drugs; H.R. 448, the "Medicare Drug Price Negotiation Act," sponsored by Elijah Cummings (D-MD), which would instruct the Secretary of HHS to negotiate with drug manufacturers the prices to be charged to PDPs for covered Part D drugs furnished to Part D enrollees during the applicable period; and H.R. 1046, the "Medicare Negotiation and Competitive Licensing Act," sponsored by Lloyd Doggett (D-TX), which would require the Secretary of HHS to negotiate prices for all drugs covered under Medicare Part D and take into account certain factors when negotiating, including: comparative clinical effectiveness and cost effectiveness; the budgetary impact of providing coverage of such drug; the financial burden on patients; unmet patient need for a drug; and total revenues and associated investment in research and development.

To watch the hearing, [click here](#).

House Committee Examines E-Cigarettes

Also, on Wednesday, the House Energy and Commerce Oversight and Investigations Subcommittee held a hearing on the public threat of e-cigarettes. The committee launched the investigation following recent reports of individuals experiencing seizures following the use of e-cigarette products, as well as other reports of e-cigarette fires and explosions that resulted in 133 acute injuries.

To watch the hearing, [click here](#).

House Committees Continue Examination of Firearms Issues

This week, the House Committee on the Judiciary held two hearings regarding firearms violence and safety issues. On Wednesday, the full committee held a hearing titled "Protecting America from Assault Weapons," and on Thursday, the Subcommittee on Crime, Terrorism, and Homeland Security held a hearing on "Community Responses to Gun Violence in our Cities."

The full committee hearing focused specifically on the issue of assault weapons and what options exist to address this contentious topic. The second hearing on community efforts to address gun violence consisted of two panels, the first featuring two Representatives, Wm. Lacy Clay (D-MO) and Robin Kelly (D-IL), and the second featuring several witnesses from the Heartland Alliance, the Milwaukee Health Department Office of Violence Prevention, Black Guns Matter, and the Community Justice Action Fund & Community Justice Reform Coalition, who shared various experiences and efforts to address firearms violence, the disproportionate impacts of firearms violence on minority communities, and generational trauma exacerbated by violent incidents, among others.

Also, on Thursday, the Ways and Means Committee Oversight Subcommittee held a hearing, "The Public Health Consequences and Costs of Gun Violence." The hearing was a more bipartisan affair than most regarding the topic of firearms violence, though it was not without moments where

members drew clear partisan lines. The hearing looked into how firearms-related violence, including suicides, domestic violence, accidental injuries, and mass shootings, affect survivors, families, and communities in terms of immediate trauma and the longer-term economic impacts on their lives and the health care system at large.

As a cornerstone of our longstanding efforts to address firearms safety and injury prevention, ACEP continues to advocate for more research into how firearms injuries affect our patients and the health care system and will continue working with legislators to address these research and knowledge gaps.

Regs & Eggs: Regulatory Affairs Blog

ACEP has a blog focused on federal regulatory affairs, "[Regs & Eggs.](#)" Every Thursday morning, while you're eating your breakfast, ACEP's Director of Regulatory Affairs, Jeffrey Davis, provides a weekly update on major federal regulations impacting emergency medicine.

On Monday, ACEP submitted a letter to the Centers for Medicare & Medicaid Services (CMS), responding to their proposed [2020 Medicare Physician Fee Schedule](#)—which was released in July. This is a major rule that affects Medicare physician payments and the [Merit-based Incentive Payment System \(MIPS\)](#). As this is just a proposed rule, CMS is collecting comments from external stakeholders and uses that feedback to help inform the final policies. You can read a summary of ACEP's comments [here](#) and the full 42-page response [here](#)—but go to this week's [Regs & Eggs blog](#) for the highlights.

CMS Responds to 42 CFR Part 2 Proposed Rule Regarding Investigations of Serious Crimes

On Wednesday, ACEP responded to a short proposed rule released by the Substance Abuse and Mental Health Services Administration (SAMHSA) related to 42 CFR Part 2-- the set of requirements that aim to protect the confidentiality of the medical records created or maintained by federally-assisted substance use treatment disorder programs (42 CFR Part 2 Programs). While SAMHSA released a larger proposed rule on 42 CFR Part 2 that ACEP is still reviewing, this smaller proposed rule would expand the scope of investigations in which law enforcement could receive confidential communications from 42 CFR Part 2 programs. ACEP opposes this proposed rule and asks SAMHSA to withdraw it. We believe that the proposed rule, if finalized, would lead to unintended consequences that are not aligned with the overall intent of the 42 CFR Part 2 regulations. Please find ACEP's full response [here](#).

CMS Releases Final Rule on Medicare Regulatory Reform and Establishes Office of Burden Reduction

On Wednesday, CMS released a [final rule](#) that would remove "unnecessary, obsolete, or excessively burdensome health regulations on hospitals and other healthcare providers." CMS states that this rule advances the agency's Patients over Paperwork initiative by saving providers an estimated 4.4 million hours previously spent on paperwork annually, with overall total provider savings projected to be approximately \$8 billion over the next 10 years.

ACEP had [previously responded](#) to the proposed rule when it was released last year. Most of our comments focused on proposed changes to the emergency preparedness requirements for health care facilities. Notably, we had expressed concern about a range of proposals that would relax current requirements for both inpatient and outpatient providers, including allowing facilities participating in Medicare and/or Medicaid to review their emergency preparedness programs and conduct training exercises every two years instead of annually. CMS decided to finalize this particular proposal in the final rule, with the exception of Long-term Care Facilities-- which will still be required to provide training annually.

Along with the release of the final rule, CMS Administrator Seema Verma announced on Thursday that CMS is setting up an Office of Burden Reduction that will look for even more ways to reduce provider burden.

ACEP Responds to 2020 CMS Hospital Outpatient Department Proposed Rule

On Thursday, ACEP responded to a CMS proposed rule impacting payments for hospital outpatient departments. In the rule, CMS proposed a major price transparency proposal that, if finalized, would require hospitals to publicly post payer-specific negotiated rates for their services.

In our letter, we state that while we support the Trump Administration's commitment to improving price transparency, we have concerns with the transparency proposals included in the proposed rule. Although we believe patients deserve meaningful information about the price of their healthcare, doing so in this manner could be unnecessarily burdensome, detract from the relevant patient cost-sharing information, and have unintended effects on the market as providers and payers are pressured to negotiate basic fee schedules. The requirement to disclose rates could lead to anticompetitive behavior by payers once they are aware of the rates that its competitors have negotiated.

We also highlight in our response the unique factors of emergency medicine that CMS must consider when proposing and finalizing new price transparency requirements.

Please find ACEP's full response [here](#).

NIH Funds \$945 Million for Opioid Research

On Thursday, the National Institutes of Health (NIH) [announced](#) that it has awarded \$945 million for grants, contracts, and cooperative agreements across 41 states through the Helping to End Addiction Long-term initiative or NIH HEAL Initiative. The trans-NIH research effort aims to "improve treatments for chronic pain, curb the rates of opioid use disorder (OUD) and overdose and achieve long-term recovery from opioid addiction." The initiative will address multiple problems that are slowing or preventing progress or addressing the crisis, including but not limited to the fact that many people with OUD do not receive appropriate treatment for their disorder, and the patients who receive medications for OUD do not stay on treatment long enough to achieve long-term recovery.



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