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The Critical Care News Summary is an update from the Roundtable on Critical Care Policy. For further information on the Roundtable, please visit our website at www.CriticalCareRoundtable.org.

Capitol Hill Events and Updates

The Pandemic and All-Hazards Reauthorization Bill

Senate Moves Closer to Bipartisan Passage of Bill Prioritizing Critical Care Planning

On Wednesday, the Roundtable on Critical Care Policy praised Senate leaders of pandemic preparedness reauthorizing legislation for including critical care as an essential component of national preparedness. The Senate Health, Education, Labor, & Pensions (HELP) Committee mark-up of the Pandemic and All-Hazards Preparedness Act (PAHPA) Reauthorization of 2011 (S. 1855) brought together a bipartisan group of Senators committed to enhancing the nation's ability to care for the critically ill and injured. The manager's amendment adds the critical care system to the National Health Security Strategy's medical preparedness goals, ensuring that critical care is prioritized in planning efforts to increase preparedness, response capabilities, availability, coordination and accessibility with respect to public health emergencies – a key Roundtable-endorsed provision. The Roundtable on Critical Care Policy applauds the bipartisan efforts of the Senate HELP Committee for taking this important step and ensuring that critical care is given sufficient consideration in future planning efforts, and for their work to improve coordination and collaboration between the public and private sector – particularly as it relates to pandemic and medical surge planning efforts. The Roundtable believes that the bill builds on lessons learned over the past five years and will provide more support for public and the private sector to work together to ensure an effective medical response.

Federal Activity

Food and Drug Administration

On Thursday, in response to President Obama's Executive Order of Oct. 31, 2011, the Food and Drug Administration (FDA) issued an interim final rule in an effort to help prevent prescription drug shortages. The rule clarifies requirements that manufacturers solely producing a drug notify the agency at least six months before discontinuing the product. For a factsheet on the rule, please click [here](#). For the full press release, please click [here](#).

Government Accountability Office

GAO issued a report on Thursday stating that the number of crucial-drug shortages, especially among cancer drugs and nutritional products, has risen. In the report, entitled "Drug Shortages: FDA's Ability

to Respond Should Be Strengthened,” the GAO recommends giving the FDA more information and more authority. There needs to be a law compelling companies to notify the FDA early when they run into manufacturing snafus that will cause production to shut down, the audit found. For the study highlights, please click [here](#). For the full report, please click [here](#).

Department of Health and Human Services

Today, the Department of Health and Human Services (HHS) issued a bulletin to provide information on the regulatory approach that HHS intends to propose in a future rulemaking regarding the “essential health benefits” that must be included in health plans that are offered in both state-based exchange plans and non-grandfathered plans operating outside of Exchanges beginning in 2014. As outlined in the 15-page bulletin, HHS intended approach to essential health benefits “incorporates plans typically offered by small employers and benefits that are covered across the current employer market.” Therefore, HHS will provide states with the flexibility to select an existing health plan to set the “benchmark” for the items and services that must be covered.

As mandated by the Affordable Care Act, states must ensure the essential health benefits package covers items and services in at least ten categories of care, including preventive care, emergency services, maternity care, hospital and physician services, and prescription drugs. HHS is collecting public input on their essential benefits notice before issuing a proposed rule. Comments to the bulletin are due by January 31, 2012. Stakeholders can submit comments via email sent to EssentialHealthBenefits@cms.hhs.gov. For the essential health benefits bulletin, please click [here](#). For a fact sheet on the essential health benefits bulletin, please click [here](#).

News and Reports

“Government shutdown dodged: Congress finds deal,” *Politico*, December 16, 2011

House and Senate negotiators signed off Thursday night on a \$1 trillion-plus, year-end spending bill, which the leadership expects to bring to the House floor as early as Friday to put to rest any threat of a government shutdown.

“Study: Many Surgeons Don't Discuss End-of-Life Care,” *FoxNews.com*, December 16, 2011

Many U.S. surgeons fail to discuss their patients' wishes in case a risky operation goes awry, and even more would not operate if patients limited what could be done to keep them alive, a survey found. But the restrictions are debated among doctors, said the survey, published in the *Annals of Surgery*.

“Escaping ICU Hell,” *National Journal*, December 15, 2011

Late-life care is arguably the most flawed precinct of a troubled medical system. It is also a sector that growing numbers of Americans will encounter, as more of us live longer. Longevity, of course, is good. But for how many of us will it mean additional years of sickness, frailty, decline? For how many will it mean more medical care than we need or want? Experts are divided on how longevity and health intersect.

“Generic drugmakers to build warning system on shortages,” *Reuters*, December 15, 2011

Generic drugmakers plan to work with distributors, wholesalers and others to create an advance warning system for medicines that are in short supply, the head of the U.S. generic industry's trade group said on Thursday. The private-sector system would supplement a notification system used by U.S. health officials to inform patients and others of looming supply problems for these life-saving medications, most of which are generic.