January 22, 2018

KOEHLER FITZGERALD

| REFERENCE-BASED PRICING NEWSLETTER |

Koehler Fitzgerald

Koehler Fitzgerald LLC provides highly specialized legal services to TPAs, HCSMs and Plan Sponsors offering reference-based medical plans.

Central to those services are the defense of balance billing claims, from provider billing to jury trial, utilizing the firm's highly rated trial lawyers, nationally recognized experts and affiliated local counsel throughout the U.S.

Koehler Fitzgerald's multilingual services are supported by the use of proprietary and customized software to track and support group calendaring, task management, contact management, conflicts checking, integrated document assembly and customized weekly reports of the status of claims and activity.

James F. Koehler
Koehler Fitzgerald LLC
1111 Superior Ave.
Cleveland, Ohio 44114
216.539.9370

Federal Right to Try Legislation

On August 3, 2017, the Senate passed the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act (S. 204) intending to expand the rights of patients with life-threatening illnesses to obtain drugs which have not been approved by the FDA. The bill is before the House and enjoys the support of V.P. Pence and libertarian groups, including the Goldwater Institute.

An eligible patient is a patient "who has been diagnosed with a life-threatening disease or condition", "who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who … is in good standing with the physician's licensing organization or board … and … will not be compensated directly by the manufacturer for so certifying." The patient or the patient's authorized representative must have provided an informed consent and the eligible investigational drug must have completed a Phase 1 clinical trial.

The bill prohibits the FDA from using negative clinical data or outcomes from eligible patients to "delay or

Dept. of Labor Proposal

On January 4, 2018, the U.S. Department of Labor issued a News Release proposing new rules allowing health insurance to be sold across state lines through small business or association health plans.

"The proposed rule, which applies only to employer-sponsored health insurance, would allow employers to join together as a single group to purchase insurance in the large group market. These improvements stand to open health insurance coverage for millions of Americans and their families by making it more affordable for thousands of small businesses and sole proprietors. By joining together, employers may reduce administrative costs through economies of scale, strengthen their bargaining position to obtain more favorable deals, enhance their ability to self-insure, and offer a wider array of insurance options.

"As proposed, the rule would:

"Allow employers to form a Small Business Health Plan on the basis of geography or industry. A plan could serve employers in a state, city, county, or a multi-state metro area, or it could serve all the businesses in a particular industry nationwide;

"Allow sole proprietors to join Small Business Health Plans, clearing a path to access health insurance for the millions of uninsured Americans who are sole proprietors or the family of sole proprietors." EBSA News Release: 01/04/2018.

adversely affect the review or approval of such drug," unless those outcomes are determined to be "critical to determining the safety of the eligible investigational drug."

The bill further provides that sponsors, manufacturers, prescribers, dispensers or other individuals shall not be liable for an act or omission "unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law."

A January 2018 article in The New England Journal of Medicine cites, and largely dismisses, two concerns. "First, despite the claim that dying patients have nothing to lose, granting very sick patients early access to unapproved products may be more likely to harm patients than to help them. Many drugs that look promising in early development are ultimately not proven safe or efficacious.

"The second concern is that, unless the requirement that patients be unable to participate in a clinical trial is interpreted strictly, expanding access outside trials may delay the generation of data needed to make evidence-based decisions about approval and use of new drugs. Even if access to investigational drugs is limited to patients who truly could not participate in trials testing them, the diversion of resources toward expanded access could have serious implications for the much larger number of patients who would benefit from expeditious approval of effective drugs."