Annals of Health Law

Volume 22 Issue 1 Winter 2013

Article 1

2013

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Annals of Health Law

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Recommended Citation

Table of Contents, 22 Annals Health L. [iv] (2013). Available at: https://lawecommons.luc.edu/annals/vol22/iss1/1

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ANNALS OF HEALTH LAW

THE HEALTH POLICY AND LAW REVIEW OF LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

Beazley Institute for Health Law and Policy

VOLUME 22, ISSUE 1

WINTER EDITION 2013

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The Curious Case of Trent Arsenault: Questioning FDA Regulatory Authority Over Private Sperm Donation			
Amber D. Abbasi1			
Recent action by the Food & Drug Administration provides an opportunity to examine the federal government's regulation of reproductive medicine. Generally, regulation focuses on contraception and abortion services. However, regulation entered a unique legal situation in the recent case of Trent Arsenault. Through a personal website, Mr. Arsenault offered semen donations to women on a purely private, uncompensated basis. The FDA subsequently ordered him to "cease manufacture" of sperm donations. The FDA's exercise of new authority requires careful examination. This article examines the regulations that the FDA seeks to enforce against private sperm donors, their application in the Arsenault case, and the implications of expanding the government's regulatory authority over individuals' procreative decisions.			
Ready or Not: Hospital Value-Based Purchasing Poised to Transform Healthcare Reimbursement Model and Introduce New Fraud Targets under the False Claims Act			
PollyBeth Hawk43			

Value-based purchasing is central to the government's mission to improve quality and achieve value for Medicare. Under PPACA, value-based purchasing programs will be used to incentivize quality improvement through payment reform. Value-based purchasing programs are based on the principle that providers will achieve better outcomes if their reimbursements are linked directly to their performance and, consequently health care will become more efficient and cost effective. This paper discusses the value-based purchasing template set forth by CMS in its Roadmap to Implementing VBP, as well as the required commitment to transparency as these changes occur. Moreover, value-based purchasing will be affected by the possibility of liability under the False Claims Act. The author explores the potential interplay between the False Claims Act and value-based purchasing programs.

A New Regulatory Strategy Against Smoking –Weekly Lotteries and Increasing Credit Balance as Incentives to Modify Behavior

Gerrit M. Beckhaus	9	7
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Tobacco use continues to affect adversely a significant number of people, despite extensive tobacco control strategies in recent decades. This article discusses the impact of current regulatory approaches as well as the critical period of smoking initiation. The author argues that smoking is a modifiable behavior. Borrowing from behavior economics theories, this article explores the possibility of providing positive economic incentives to affect people's choice regarding tobacco use. Focusing on the United States as a background, the proposed model takes a dual approach consisting of a weekly lottery as well as an account with an increasing credit balance than can only be accessed after a specific period of non-smoking.

Is Sugar the New Tobacco? How to Regulate Toxic Foods

Barbara L. Atwell	13	2 Q
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The average American diet is subject to both increasing scrutiny and criticism. In this article, the author focuses on the risks associated with excessive consumption of added sugar and what is to be done to address this public health problem. Obesity, heart disease, diabetes, and other chronic diseases have been linked to diets high in added sugar. These diseases both reduce quality of life and cost the healthcare system a considerable amount of money. Recently, attention has been drawn to the government's role in regulating food choices. The author examines the evidence of health risks associated with added sugar and why, despite such evidence, the food industry perpetuates the problem. The author then explores whether added sugar ought to be a regulated substance, discussing the benefits and drawbacks of such regulation. A comparison can be drawn between proposed added sugar regulations and tobacco regulations. The author argues that many of the laws designed to discourage tobacco use should be applied to products with large quantities of added sugar.

Hospital Value Based Purchasing and the Bundled Payment Initiative Under the Affordable Care Act: A Good Start, but is it Good Enough?

Jarg		

Health care reform discussions frequently center on improving quality while containing costs. The current reimbursement structure, and its reliance on fee for service payments, is often cited as negatively affecting these two goals. This article discusses federal efforts to reform the health care system's current fee-for-service reimbursement structure. Two programs under PPACA, Hospital Value Based Purchasing and the Bundled Payment Initiative, aim to contain escalating costs while improving the quality of care provided. Both programs are Medicare-based and link reimbursement with outcomes rather than provision of services, thereby attempting to incentivize efficient, high quality care. The Hospital Value Based Purchasing program does so by using a pay for performance model while the Bundled Payment Initiative uses an episodic payment model. The author argues that the structure of these programs will be inadequate to accomplish the federal government's stated goals. The programs should not be abandoned, but significant modifications may be necessary in order to avoid failure or unintended consequences.