



ComplianceConnection

August 11th, 2014



Shasta Technologies GenStrip Blood Glucose Test Strips May Report False Results: FDA Safety Communication



Purpose:
The FDA is advising people with diabetes and health care professionals to stop using GenStrip Blood Glucose Test Strips because the strips may

DOL Investigating Outsourcing of Employee Benefit Plan Services

The Department of Labor says it is investigating the outsourcing of employee benefit plan services, including its legal framework under the Employee Retirement Income Security Act, and benefit industry insiders are urging the department to remain flexible on the subject.

The DOL's ERISA Advisory Council said last week it plans to identify current industry practices and trends regarding the types of services being outsourced and the market for delivery of those services as part of its 2014 issue agenda.

Based upon testimony from benefit industry experts, the Council will submit recommendations to DOL Secretary Thomas Perez about current best practices in selecting and monitoring outsourced service providers, including possible performance standards, the benchmarking of costs, and mitigating conflicts of interest. In their written testimony benefit experts are urging the council to consider the complexity of outsourcing benefit administration and consider



report incorrect blood glucose levels. The FDA recommends the use of alternative glucose test strips that are designed for use with the LifeScan OneTouch family of glucose meters.

Summary of Problem and Scope:

During a recent inspection of Shasta Technologies LLC, the FDA found extensive violations of federal regulations intended to assure the quality of products in the manufacturing of GenStrip Test Strips. These regulations, called quality systems regulations, require manufacturers to establish and document procedures that assure quality, including ways to deal with customer complaints, adverse event reports, and purchasing from suppliers. These regulations also require manufacturers to establish and document procedures for assuring the quality of manufactured product, and for investigating and correcting manufacturing problems.

[Continue reading ...](#)

Juvenile Arthritis: New Discoveries Lead to New Treatments

Juvenile arthritis is one of the most common chronic illnesses affecting children. In fact, nearly 300,000 youngsters nationwide have been diagnosed with the disease. The most common symptoms include joint pain,



flexibility within its recommendations.

"Outsourcing will mean different things to different people and companies and in the context of different benefit plans," says Allison Klausner, assistant general counsel of benefits for Honeywell International Inc., in testimony submitted on behalf of the American Benefits Council, of which she is a member and officer of the executive board.

"For this reason, in particular, flexibility must be a key component of any government or company initiative to shape the selection and monitoring of a supplier to whom a portion of the plan function has been outsourced," she adds.

[Read more ...](#)

Clarification of Medicaid Coverage of Services to Children with Autism

In response to increased interest and activity with respect to services available to children with autism spectrum disorder (ASD), CMS is providing information on



approaches available under the federal Medicaid program for providing services to eligible individuals with ASD.

Background

Autism spectrum disorder is a developmental disability that can cause significant social, communication and behavioral challenges. A diagnosis of ASD now includes several conditions that used to be diagnosed separately: autistic disorder, pervasive developmental disorder not otherwise specified (PDD-NOS), and Asperger syndrome. These conditions are now all called autism spectrum disorder. Currently, the Center for Disease Control and Prevention (CDC) estimates that approximately 1 in 68 children has been identified with ASD.

inflammation (swelling), tenderness and stiffness. One early sign may be limping in the morning.

[More ...](#)

[For more ...](#)

About Our Newsletter

As a continued service to you, we will distribute the Compliance Connection on a bi-weekly basis. As pertinent compliance issues arise we may distribute information off-cycle. Thank you!

Hamilton Insurance Agency
4100 Monument Corner Drive
Suite 500
Fairfax, Virginia 22030

p) 800.275.6087
e) compliance@hamiltoninsurance.com
www.hamiltoninsurance.com

Please note that Hamilton Insurance does not provide legal advice, and this not constitute advice of any kind for any particular situation. Instead, this is intended as non-comprehensive general information serving as a starting point for further discussion. Please contact your tax and/or legal advisors for information about how these issues affect you.



[Forward this email](#)



This email was sent to jmoyer@hamiltoninsurance.com by compliance@hamiltoninsurance.com | [Update Profile/Email Address](#) | Rapid removal with [SafeUnsubscribe™](#) | [Privacy Policy](#).



Try it FREE today.

Hamilton Insurance Agency | 4100 Monument Corner Drive | Suite 500 | Fairfax | VA | 22030