

## Special Investigations Unit (SUI) Updates: FDA Warnings

Published: Sep 28, 2018 - Administrative

The Special Investigations Unit (SIU) is tasked to conduct investigations involving allegations of fraud, waste and abuse, to work with our providers to resolve billing practice issues in order to reduce or eliminate future payment issues, and, where appropriate, to recover overpayments.

As part of Anthem's role to safeguard our members and provide relevant information to providers we are relaying the following recent Food and Drug Administration (FDA) Warning Letters:

*Estring* - On June 19, 2018 the Food and Drug Administration issued a letter of warning to Pfizer for "false or misleading" promotional materials related to ESTRING® (estradiol vaginal ring). According to the FDA the posted "... video is especially concerning from a public health perspective because it fails to include **any** risk information about Estring, which is a drug that bears a boxed warning due to several serious, life-threatening risks, including endometrial cancer, breast cancer, and cardiovascular disorders, as well as numerous contraindications and warnings. The video thus creates a misleading impression about the safety and efficacy of Estring".

*Xtampza ER* --On February 9, 2018 the Food and Drug Administration issued a letter of warning to Collegium Pharmaceuticals for publicly providing false or misleading representations regarding Xtampza (oxycodone) ER because it "fails to adequately communicate information about the serious risks associated with Xtampza ER use".

Further details regarding these Warning Letters from the FDA can be obtained from the [FDA website](#):

- [Information about Estring](#)
- [Information about Xtampza ER](#)

URL: <https://providernews.anthem.com/indiana/article/special-investigations-unit-sui-updates-fda-warnings>

**Featured In:**

October 2018 Anthem Indiana Provider Newsletter, October 2018 Anthem Kentucky Provider Newsletter, October 2018 Anthem Missouri Provider Newsletter, October 2018 Anthem Ohio Provider Newsletter, October 2018 Anthem Wisconsin Provider Newsletter

Anthem Blue Cross and Blue Shield is the trade name of: In Colorado Rocky Mountain Hospital and Medical Service, Inc. HMO products underwritten by HMO Colorado, Inc. In Connecticut: Anthem Health Plans, Inc. In Georgia: Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. In Indiana: Anthem Insurance Companies, Inc. In Kentucky: Anthem Health Plans of Kentucky, Inc. In Maine: Anthem Health Plans of Maine, Inc. In Missouri (excluding 30 counties in the Kansas City area): RightCHOICE® Managed Care, Inc. (RIT), Healthy Alliance® Life Insurance Company (HALIC), and HMO Missouri, Inc. RIT and certain affiliates administer non-HMO benefits underwritten by HALIC and HMO benefits underwritten by HMO Missouri, Inc. RIT and certain affiliates only provide administrative services for self-funded plans and do not underwrite benefits. In Nevada: Rocky Mountain Hospital and Medical Service, Inc. HMO products underwritten by HMO Colorado, Inc. dba HMO Nevada. In New Hampshire: Anthem Health Plans of New Hampshire, Inc. HMO plans are administered by Anthem Health Plans of New Hampshire, Inc. and underwritten by Matthew Thornton Health Plan, Inc. In Ohio: Community Insurance Company. In Virginia: Anthem Health Plans of Virginia, Inc. trades as Anthem Blue Cross and Blue Shield in Virginia, and its service area is all of Virginia except for the City of Fairfax, the Town of Vienna, and the area east of State Route 123. In Wisconsin: Blue Cross Blue Shield of Wisconsin (BCBSWI), which underwrites or administers the PPO and indemnity policies and underwrites the out of network benefits in POS policies offered by CompCare or WCIC; CompCare Health Services Insurance Corporation (CompCare) underwrites or administers the HMO policies and Wisconsin Collaborative Insurance Company (WCIC) underwrites or administers Well Priority HMO or POS policies. Independent licensees of the Blue Cross and Blue Shield Association. Anthem is a registered trademark of Anthem Insurance Companies, Inc. The Blue Cross and Blue Shield names and symbols are registered marks of the Blue Cross and Blue Shield Association. Use of the Anthem websites constitutes your agreement with our Terms of Use.

---